IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
AARON MICHAEL SHAMO,	)	Case No: 2:16CR00631
	)	
Defendant,	)	
_____	)	
	)	
	)	

BEFORE THE HONORABLE DALE A. KIMBALL

August 22, 2019

JURY TRIAL
TESTIMONY OF STANLEY FRANK PLATEK
TESTIMONY OF NICOLA RANIERI
TESTIMONY OF ADAM LANZAROTTA
TESTIMONY OF HEATHER ANNE McCAULEY
TESTIMONY OF ARTHUR SIMONE

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I N D E X

SALT LAKE CITY, UTAH, THURSDAY, AUGUST 22, 2019

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THE COURT: Are we ready to proceed?

MR. SKORDAS: Yes.

08:30:50 THE COURT: We'll get the jury and proceed.

(Whereupon, the jury returned to the court proceedings.)

THE COURT: Good morning. Welcome again. Thank you for your work.

08:32:26 The government may call its next witness.

MR. BURGGRAAF: United States would call Frank Platek.

THE COURT: Come forward and be sworn, please.

THE CLERK: Please raise your right hand.

08:32:42 STANLEY FRANK PLATEK,

called as a witness at the request of Plaintiff, having been first duly sworn, was examined and testified as follows:

THE WITNESS: I do.

08:32:52 THE CLERK: Please come around to the witness box. Please state your name and spell it for the record.

THE WITNESS: Yes. Stanley Frank Platek. S-T-A-N-L-E-Y F-R-A-N-K, Platek is P-L-A-T-E-K.

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08:33:32 //

DIRECT EXAMINATION

BY MR. BURGGRAAF:

Q. Mr. Platek, thanks for being here this morning. As you are aware I sometimes pronounce things incorrectly, and you feel free to correct me if I do.

Can you tell me your current occupation is and where you're employed?

A. Yes. I'm employed with the US Food and Drug Administration's Forensic Chemistry Center as a biologist in the trace evidence section.

Q. And how long have you been employed by the FDA?

A. I've been employed by the FDA for over 28 years.

Q. And in your current positions what are your job responsibilities?

A. Mostly to handle anything related to tampering, particle analysis and to be a lead analyst when so designated for any type of samples that come in related to my areas of expertise.

Q. And what's your educational background?

A. I have a Bachelor of Science degree from Murray State University in biology with a minor in chemistry. I have a Master of Science degree in Industrial Hygiene from the University of Cincinnati College of Medicine.

Q. What additional training do you have that relates to your current position with the FDA?

A. I have had numerous courses and training classes throughout my career with the government of over 43 years. I have several courses in toolmark examination, a two-week course with the Indiana State Police and a one-week course with the safety institute of Ohio's Department of Justice operation, in which they instructed the full analysis of toolmarks.

Q. And do you provide training to others?

A. Yes. I provide training in a number of other areas. I've been a faculty instructor at Northern Kentucky University in northern Kentucky since 1982. And I teach scanning electron microscopy and energy-dispersive x-ray on microanalysis. I also teach at the Lehi University Microscopy School, and I've been doing that since 2005.

Q. And what professional organizations do you belong to?

A. I'm a member of the academy -- American Academy of Forensic Scientists. I am a member of the Midwestern Association of Forensic Scientists. I'm a member of the Ohio Valley Microscopy Society, and I'm also a member of the Microscopy Society of America, in which three years ago I was honored as a fellow of that society.

Q. And have you testified as an expert before?

A. I have.

Q. How many times?

A. Three times. State and federal.

Q. And has the Court ever made a finding that your testing methods or results were not accurate or correct?

A. No, sir. That is correct.

08:36:31 Q. Have you had any experience analyzing pill press punches and dies?

A. I have.

Q. What did you do to prepare for your testimony today?

08:36:43 A. Reviewed my notes, thought about the manner in which I would present. But normally it would just be review what I've done and how I put my worksheets together.

Q. And you've had a couple of less than full nights of sleep, as well.

08:36:56 A. That's true.

Q. Okay. Let's speak more generally -- first, how did you become involved in this case?

A. The case was assigned to me by our supervisor from the trace evidence section. We rotate how often different

08:37:15 people take positions as a lead analyst in a case, and for this particular one since it would need an initial microscopy front end and some of the additional physical examinations I was assigned to take the sample.

The sample was picked up from our sample custodian

08:37:37 in the laboratory where I signed for it to maintain chain of

custody. I take it to our laboratory. And at that point the sample is -- we have several forms that we put together that are part of our procedure for bringing new samples into the laboratory. And we take those. Those were prepared. We identify the seals, and then we go through a full photo documentation of each of the items as received. We don't open anything. Everything is photo documented.

And at that point we will be getting information from both the information provided by the special agent as to what their request was for analyses. They will also -- in conference we take a look at what the evidence may be, say, we might suggest we could do this. They say, we would like this. We may not be able to perform some of those with what's provided or we might need more information. So we will be in contact with the special agent or submitting agents in these cases.

And at that point we decide -- it's sort of a triage as to how a sample is going to be addressed. If you're going to do a destructive technique on something you can't do that destructive technique first and then take it on and hope to do something else. So we decide who is going to receive which portions of a sample and for what reasons.

Q. I want to kind of backup just a little bit as far as speaking more generally about the FDA lab, which I'm referencing as the FDA lab the forensic chemistry center.

A. Correct.

Q. First of all, is the lab a certified or national accredited lab?

A. We are. We are an accredited forensic laboratory. We are accredited through a group that's all A-NAB and the ANAB. And the A in ANAB stands for the American National International -- I'm sorry. We converted about a year and a half ago. The American National Institute of Standards. And then the NAB part is National Accreditation Board.

08:39:47 Q. I'm not going to ask you for every specific requirement. But what's typically required to become an accredited lab?

A. Obviously having a secure forensic security with full chain of custody from time in to time out. We have

08:40:02 procedures in place for all instrumentation. We have analysts that are determined through testing to be proficient in the disciplines in which they are working. We get annual tests in specific disciplines based upon what we are doing in the laboratory. And it's a -- some of them are very rigorous, and

08:40:25 you must pass it to go on. They are ways to handle it if there are issues with that. There have not been problems along those areas.

We also have to have a facility set up in such a manner that the analyses can be performed in a safe fashion

08:40:42 under safe working conditions. The sample security is very

high priority with us. And there are a number of other ones as far as procedures, how you handle things, at the ANAB rules and regulations, as it is with any forensic accreditation board are very stringent. And it takes truly years to be prepared to be ready for one.

Q. What types of equipment or instrumentation is utilized at the lab?

A. We have -- with all bragging rights among scientists, we have an incredible array of instrumentation in our laboratory. For the microscopy side we have almost every type that is available. I say almost. We have everything from your basic light microscopes to scanning electron microscopes. We are equipped with all types of spectrometers. We have infrared analysis instrumentation. We have gas chromatography, mass spectrometers, we have inductively coupled plasma emissions spectrometer used for analyzing for elements. There are a lot of these different types of instruments in the laboratory, and that doesn't begin to touch them all. A lot of these we have in duplicate and triplicate because of the fruit put through the laboratory and what we do. You need to have a lot of instruments.

All instruments are certified. We also have a procedure in which if an analyst is going to use that instrument that day they must perform a performance validation of that instrument. You can't assume that it's going to work

properly. And every day if you're going to use it you have to log in onto it, you have to perform the test with a certified standard, whether it's chemical or physical. It's recorded in two places, one in the logbook right at the instrument, and one goes on to our quality assurance folder which is on the laboratory server. And again, once it goes in it cannot go out.

Q. Is there standard policies and protocols for ensuring that the instrumentation and equipment is properly sterilized?

A. Sterilized, we do not do sterilization with the exception of our biological safety laboratory 3. We have a full BSL 3 laboratory at the forensic chemistry center, and that's handled for the microbiologist.

But as far as cleaning, preparation, making sure that the samples are used, absolutely, that the surfaces are wiped. I will exchange backing papers between samples to prevent cross-contaminations, just as an example.

Q. Now, you mentioned quite a few protocols and policies in how the lab operates. As the lead analyst and to your knowledge were those policies and protocols followed in the analysis in this case?

A. To the best of my knowledge, yes.

Q. Are the processes and tests and methods for analyzing items in the lab commonly accepted and considered

reliable in the scientific community?

A. They are, yes, sir.

Q. While using the lab equipment to analyze and exam items in the case did you have any indication that any

08:44:13 equipment was not operating properly?

A. No, sir.

Q. Are the labs results found by one analyst confirmed by another?

A. They are definitely confirmed. Every analyst who

08:44:22 is assigned a portion of the sample to analyze will perform their analyses. They will prepare a worksheet section, and it will be called an analytical section. They will perform that section, and that section is not only checked but fully reviewed by another member of the forensic chemistry center

08:44:40 who is proficient in that technique. You want to have somebody who knows what you're doing review your work. And they'll make sure that everything both scientifically is correct, that your calculations are correct, every single one of them, and that, quite honestly, the right form is used.

08:44:56 All analytic information is in there. We do have SOPs on that, as well.

Q. What does SOPs stand for?

A. Standard operating procedure.

Q. Okay. Let's get a little more in-depth in this

08:45:08 specific case. You mentioned retrieving items as well as a

request after being assigned as the lead analyst in this matter.

A. Correct.

Q. What items specifically -- how are the items labeled that were requested to be analyzed?

A. I received 22 items, and they were each in individual evidence bags, sealed evidence bags. One side of the evidence bag had a DEA label, evidence label on it, the opposite side had an OCI, our office of criminal investigation label. Each bag also had a tape over the seal end with the FDA OCI number information on it, as well. And all bags were sealed, received sealed.

Q. Now you referenced a DEA label on the front of it. I would like to approach and present you with Government's Exhibit -- let me make sure I've got the right number here -- 7.43.

Now, I'm not going to ask if you recognize that specific exhibit. But the label on the front of that, does that look similar to the DEA labels that were on the 22 items that were received?

A. It does. Including the one on the vial that's inside here.

Q. And the labels that were on the 22 items that you received similar to this label, did it have a DEA exhibit number listed?

A. Yes, it did. On this -- just like this one right here.

Q. Okay. Thank you.

In preparation for your testimony did you take the time to list out essentially what the items were that were received and the general categories?

A. I did.

Q. Did you do so on that white pad?

A. I did. In advance of this I prepared for easier demonstration.

If I may get up, Your Honor?

THE COURT: You may as long as you speak up.

MR. BURGGRAAF: And, Your Honor, I believe he's going to stay in his seat. He is just going to flip the paper over so the jury can see how he listed it out.

THE COURT: Okay.

Q. BY MR. BURGGRAAF: Can you explain to the jury what it is they're looking at there that you listed?

A. Yes. If you take a look at this, on the very top line it says, Items 1 through 5, 7, and 11 were all tablets in which the debossing on the tablets, the marks that are down into the surface of the tablet, had the A and 215. It also had a half score on this.

The next lines down is Items 6, 8, 9, 10, 12 and 13, and those were debossed with a capital M that is enclosed

within a square, and the square has slightly rounded edges, and the number 30 on the opposite side with a half score.

The next line down is Items 14 through 19. And these were oblong tablets that were marked GG249 on one side with three, what we call, quarter scores. There were three separate marks on there. And the backside of that tablet had nothing on it.

The next one is Item 20. There were two tablet punches in there that were also marked with the GG249. Now these were embossed. It's a negative image of what would have been on the tablet. And they were embossed with the GG249. Included with that were other tablet punch tips, et cetera, even five tablet dies. And dies are another part of the tableting process that were included with that sample.

The Item 21, there were 9 punches that had the M, capital M with the square with the rounded corners. And tablet -- or Item 22 were 8, again more tablet punches, and these were all with the embossing GG249.

Q. So the last three items contained punch or punch tips.

A. Right. The punches with the tip on the end of it, correct.

Q. Now you mentioned Item 20 that there were two punch tips with the GG249. You've got it separate there. Why haven't you listed out the additional punches?

A. The reason we have not listed the other ones here is we did not have corresponding tablets for comparison for any of the other punch tips that were included with that sample.

08:50:10 Q. I want to start with Items 1 through 5, 7 and 11. You've got it listed that they were each debossed with A215. In each of the items both on that first line and the next two that reference pills or tablets, how many of those pills or tablets were in each item?

08:50:31 A. Each item came with five tablets for all Items 1 through 19.

Q. And do you know where those tablets came from before being at the FDA lab?

A. No, I was not. I was told they would be coming

08:50:46 from DEA when we saw the evidence, but that was the extent of it.

Q. So the first line you've got the debossed tablets with A215. Do you know what the A215 means in the pharmaceutical world?

08:50:59 A. In the pharmaceutical world this one would refer to an Oxycodone tablet.

Q. And the next line down, the M or M box with the 30, do you know what that --

A. That's also an Oxycodone embossment.

08:51:16 Q. And the GG249, do you know what that signifies?

A. Yes. Alprazolam.

Q. So as the lead analyst in respect to the requested analysis, what was your role?

A. My role as lead analyst in this one was as I mentioned before to evaluate the sample as I first receive it, document how I first received it, and then I will upon deciding once we've talked with other analysts and other supervisors how they want us to approach the analyses on these, I would open the sample, and we have a protocol, we will put our initials and a date and we will open it directly on the bag, and then the samples were removed.

In the case of Items 1 through 19, those tablets were received in small glass vials with a white top. And the tablets were removed from those. So this was done in a fume hood now because we weren't sure what we were dealing with. And we would have a 50 millimeter, which is about 2 1/2 inches in diameter petri dishes that have forcible lids. The hold on. We use these a lot in the laboratory. They're new. They're fresh. They're brand-new out of the package, and they're sterile when we do receive them.

We open one of those up after labeling it, and then the five tablets we put in there and put the seal. And then all -- once that was done with all of the samples with their own individual item petri dish were put into a plastic snap lid container, and that was retained, and since we've

opened it in a hood.

Q. And is that container then labeled to ensure that items stay separate and clearly identified?

A. Yes. Each one is individually identified within there, yes, sir.

Q. So let me take you back just prior to this portion. You mentioned and kind of confirmed that each of the items came in a separate evidence bag; is that right?

A. Yes.

Q. And they had multiple labels on it?

A. Yes.

Q. I want to reference the DEA label that you mentioned. You mentioned that it had the DEA exhibit number listed.

A. (Witness indicates by nodding head up and down.)

Q. On Item 1, did that label have DEA Exhibit Number 14 noted on it?

A. I would have to look in my records to confirm that for Item 1.

Q. Did you note that -- did you note down what DEA --

A. The DEA numbers were not noted, but they are captured for the photos for with each one of the items. It will be on the bag.

Q. Okay.

A. And I do have that in my record in my Section 1.

Q. Okay. Section 1.

MR. BURGGRAAF: If I may approach?

THE COURT: You may.

THE WITNESS: Thank you.

08:54:54 Q. BY MR. BURGGRAAF: Mr. Platek, I think if you can look at Item 1 and explain to the jury what DEA exhibit number is listed.

A. Exhibit Number 14.

Q. And Item Number 2, what DEA exhibit number is

08:55:07 listed?

A. Item 34.

Q. And Item Number 3, which DEA number is listed?

A. I'm sorry. You're printed on both sides here.

Item 1 was 14; Item 2 was 34; Item 3 was 64; Item 4

08:55:38 was 123. Do you wish me to go on?

Q. Yes. Please go through Item 22.

A. Sure. Item 5 is 193; Item 6 is, it looks like 45.

Q. Is it possible that that's an 85?

A. The first character is slightly squiggled. Let me

08:56:05 take a look and see if I can look on a different portion of that. Yes. If I look up on the yellow label it's 85.

Q. Okay.

A. And Item 7 appears to be 95; and Item 8 is, it looks like they have it as Exhibit 85.02.

08:56:38 Q. Could that be 95.02?

A. That is hard to read. It could be a 95 on this one. The yellow tag above it does have 95 for the exhibit on it. I apologize.

Item 9 is 96; Item 10 is 136; Item 11 is 174; Item 12 also has 174 on it; at least on their exhibits here; Item 13, 188; Item 14, 54; Item 15 is Exhibit 15; Item 16 is Exhibit 97; Item 17 is 126; Item 18, 173; Item 19, 185; Item 20, 177; Item 21 is 178; and Item 22, 179.

Q. Now, the jury previously heard testimony about each of these exhibits and several of them that were tested by the DEA lab. The testimony for multiple items that you went over, they heard testimony that was positive for the presence of Fentanyl while others were positive for the presence of Alprazolam.

When you documented those items in their evidence bags did they have any sort of cautionary label?

A. Yes, sir. The first three appear on the Items 1 through 5 had a cautionary label on there that said Fentanyl. Now, Items 1 through, I believe 1 through 13 had a caution label on it. But they all did not necessarily have anything else handwritten on them. The remainder of them, Items 14 through 19 did not have a caution on the bag.

Q. And Items 20, 21, 22, did they have any sort of cautionary label?

A. Not to my recollection, no.

Q. What precautions -- seeing those precaution labels, did you take any additional precautions on how the items are handled?

A. We do. Whenever there's a concern of Fentanyl the samples are handled in a fume hood. We'll keep them in that area as much as possible while we're processing them. As I mentioned when they were opened they were done in a fume hood. The samples in the case of the tablets are kept in petri dishes until they have to be opened, say, under a microscope or whatever. And aside from that they're closed and retained in the one area.

Q. Now, you mentioned after the items were removed from the evidence bag that they were then photographed.

A. They were.

Q. What type of instrument was used for photographing the items?

A. The initial one was done by stereoscopic light microscopy. And I positioned three tablets trying to show at least two with the debossing and one with the backside of the tablet for verification.

Q. Can I abbreviate that by saying SLM?

A. SLM, that is correct.

Q. Because I'm probably going to get it wrong if I say it otherwise.

What type of tool is this?

A. It's a microscope, and you've seen them on TV on forensic files. It's a large binocular microscope that you can look into. Very high-end lenses inside of those, glass lenses. We can light below from underneath. We can project lights on the top, and we even have cable arms and wands that we can put fiberoptics directly onto the tablets or whatever we're examining.

Q. And that's used to actually take the photographs?

A. We do. The system is also included with a very high-end digital camera, which is located on the top of this microscope. It makes it actually a safer way for us to do this because we don't have to put our face where our eyes are here and samples are here close to your face, we can put it down here. We can be back from it and actually use a mouse and a screen, and we can see exactly what we're going to capture using a camera and capture those images. It's the same way if you were putting a cell phone up there and collecting those images on a large monitor.

Q. Let's look through a few of those photographs that you took. If we can look at Government's Exhibit 24.01.

Is this one of the photos you took?

A. It is.

Q. And what is it depicting?

A. This is an image of three of the tablets of the A215 type that you see on the top over here. And the two on

the right show the debossed surfaces with the half score that I mentioned. The tab on the upper left is the same thing on the other side. But this one is showing the backside of the tablet to show there is nothing on the backside of that tablet.

09:03:21

Q. Now you mentioned previously that in each item there were five tablets. Why are there only three depicted in this photo?

A. The lowest magnification that I can use on the stereoscopic microscope and capture this type of image is done, and that's the largest field I can get. If I tried to put any more tablets into this field they would then be shoved out and you would have seen partials. In fact, you're seeing that the very bottom of one of the tablets, is slightly covered. You just can't quite squeeze it all in. But it was meant to be representative to show what the tablets looked on both sides.

09:03:35

09:03:52

Q. Let's look at 24.02.

Is this one of the photos that you took?

A. Yes, sir, it is.

09:04:09

Q. What is this depicting?

A. This is depicting the type of tablets that you see in the second line over here with the M in the large square with rounded edges, and the backside has the 30 on it, the debossed 30 with a half score.

09:04:22

Q. And let's look at 24.03.

A. Now these are oblong tablets, and these are from the bottom one over here from Items 14 through 19 representative of those with the GG249 with the three-quarter scores. As you see, there are only two tablets in this one. For the same reason, these are larger tablets and we could only get those into the image as you see here.

Q. And let's look at the next photo 24.04. What are we looking at here?

A. Now this is a tablet punch tip. And if you will notice on it the upper right you can see the inverted GG that we're talking about over here, and then the next block coming down you'll see a 2 inverted. The next one down you'll see a 4 inverted, and at the very bottom you'll see the 9 inverted. This is the tablet punch tip with the embossed features. The embossed features are the ones that are sticking up that will make the debossed features into a tablet once it's pressed. And this is representative of those.

Q. Let me look at Exhibit 24.05. And what are we looking at here?

A. This is another one of the tablet punch tips representative of the type over here that we had with the 20 -- Item 21. And you'll see we had nine of those. Those have the M, capital M enclosed within the rounded-edge square. And this type of appearance that you see here you're seeing

the actual M. Again, it's the punch tip itself.

Q. And it looks like there's some sort of white substance that's on the punch tip. Were you able to identify what that was?

09:06:22 A. We did not. But there's so much -- there's contamination on things. We see loose particles of stuff, we do not collect in this particular area. But the images that were captured initially were of the punch tips as received. This is how we got them into the laboratory. This is what 09:06:41 they looked like. They were clean before processing.

Q. So after you've identified and paragraphed the items that were received for analysis then what did you do?

A. Well, the work that I was going to do? My next job on this one was to process these and prepare these images or 09:06:59 these tablet punch tips for analysis by, it's called 3D image analysis. And what we would do with the 3D image analysis will be explained by someone else. But it was my job to prepare these.

What we would do is we actually -- I would clean 09:07:17 the surface of these, and some of the material will wash off with a little bit of water and little bit of squirt bottle. This is all done in a hood where the liquid is collected and sent to hazardous waste afterwards. But I would clean the tip of it off because we didn't get all of the particles out of 09:07:36 the or the deboss -- or the embossing that you see on the

punch tip, we would take a small cotton swab. It's on a wooden dowel that we use in the laboratory all the time, a clean one of those that's wetted with a little more water. And then we would wipe the surface, get it cleaned off. And
09:07:51 if we still couldn't get the stuff out as much as we could, you can actually take these wooden dowels, and you can snap them, and it forms a very nice little probe. It's a soft wood, and you can actually flair it a little bit so it becomes kind of like a whisk. And you can take that with water
09:08:11 squirted on there and use that to get as much as possible of the residue on the surface of these tablets removed. Then it was wiped off with a chemlight, a little lab light that we use, dried and then passed on for additional processing.

For additional processing, we want to be able to
09:08:32 compare the information, the embossed information on these punch tips to the tablets. Well, you could if you wanted to try to take a punch tip and look at it directly inverted under a microscope, capture an image and then process and try to compare images of that to the tablets. But you have to be
09:08:51 able to turn it over completely. You have to do a mirror image of it flipping your head.

So what we did we developed a method a while back in which we wanted to be able to take a look at what the tablet would look like if it was produced by that punch tip.
09:09:07 So in order to do that, we developed a method using Mikrosil.

And Mikrosil, it's M-I-K-R-O-S-I-L. Mikrosil is a product that is commonly used in the forensic community for transferring toolmarks, anything from screwdriver marks on a door lock hasp or something in which an investigating agent or
09:09:32 detective wants to collect information from that crime scene they will take the Mikrosil. It comes in two parts, there's the Mikrosil itself, and there's a hardener. And you put down equal lengths of the material. You mix it up just like you would an epoxy that you're going to do to make a repair on
09:09:52 something at home, you mix it up, and you have a little bit of time. It doesn't set up real, real fast. But you smear it on the surface of whatever. You allow it to sit on that surface for a while. And then when you remove it it comes off as a silicone mold. It all comes off beautifully and completely,
09:10:07 and it has a good permanence to keep it around for a while.

What we did is we developed a method to develop Mikrosil to make essentially -- we're taking tablet faces the way the tablet punch tip would make that particular tablet if it were there. But instead of using tablet material we're
09:10:27 using the Mikrosil.

And I would take a punch tip and invert it so it was pointed up in the air and the punch tip was up above me. We would mix up the Mikrosil, and we dab. We just don't smear it on like we're smearing butter because you won't go down
09:10:43 into those little pockets, in little places and indentions.

You'd have to do a lot of sticking and stuff like that to make sure you're getting everything well coated. Then a little bit, leave a little bit of a bleb of the Mikrosil above it. And then the remainder of the material of the Mikrosil that you mixed up is in a plastic petri dish just like we've described before, take that and invert that and put that down smoothly and flatly on the top of that surface, and then leave it alone for 20 minutes to an hour.

When you come back and remove it, it pops out just beautifully. You'll have a perfect rendition of that surface down to micro details. Mikrosil does a beautiful job of transferring even very, very small striations or marks or blemishes or irregularities in the surface of any feature that it's used on.

It comes in a number of colors. There's a brick red, a black, a white and a grey. We determined a while back that the grey was the best because it let's us see the features well, but we don't get high reflectance in the microscope back into the -- to distort images or cause problems during analysis.

And then these were capped over with the top the petri dish that's label with whatever punch tip was used to make that. It will have the sample number on it. It will have the item number on it. It will have the date in which it was prepared. It will have my initials on it. And then since

we did multiples we would do them as Roman Numeral I, Roman Numeral II and Roman Numeral III.

Q. For which punch tips did you actually create these Mikrosil capsules?

09:12:22 A. I did if for all of the ones we have identified over here. All of the GG249s, and all of the M encased in the rounded-edge circle.

Q. And how many casts for each punch tip did you do?

A. Three.

09:12:44 Q. Why do you do three?

A. We do three for several reasons. Number one, you can't always tell right away when it goes to the 3-D images equipment, it's profilometer, which will be discussed later. But you can't tell just by glancing at it real quickly if

09:13:00 there are small bubbles or something in the surface of it. We've gotten to where we're really quite good at it. But if you see some, it's rejected and we make another one. That's the beauty of it. You can make all that you want to because you're not hurting anything.

09:13:13 But in this case we try to get three that look the best. So you would be able to have repetitive -- you know, if there is an irregularity uniqueness to this punch tip that we would be making multiple copies of that that could also be determined, yes, this is consistent between these punch tips.

09:13:30 Q. So at the lab where you work more often than not

you're working in teams; that is right?

A. Yes, sir.

Q. And as a lead analyst you're responsible for kind of coordinating amongst the other analysts?

09:13:45 A. I don't coordinate it. I'll be the pressure. Where is your analytical section, because it's -- I'm the one who has to prepare the final report. But everyone is given their sample whether they were given tablets or whether they were given punch tips or anything. I do not follow them in

09:14:03 their work or their analyses. They go on. They process theirs the same way I did mine for their techniques. And once they have completed it they would have to have their work checked and reviewed. And then they get back what's called an analytical report for their discipline, for their section.

09:14:23 And that goes into our record. It's all logged in.

What I will do as the lead analyst is in the end I will, of course, include all the information that I put in here plus the identification information of the items that were within the sample as received. But I will also include

09:14:39 the lines from their verbiage from their analytical reports as to what their findings were, synopsized into a small sentence or a couple sentences or paragraphs. That all goes into the final report.

That report is then reviewed by my superior and by

09:14:59 another person who will go through and make sure that

everything is correct. They will review all of the analytical sections that were part of this particular work. They'll review what has been done there. And they will also make sure that, again, the correct forms were used, that it's clear, that it's understandable. And before anything even leaves every analyst who submitted a portion of their work, their section that was contributed to that analytical work has to sign off on the final report, as well. And there's a place on there for their name, and their analyst number goes on there so that you know that they were part of it and you could follow which work they had done. We can backtrack it that way.

Q. How many analysts were involved in performing tests or examining these items?

A. If I may look at this to count, I have to take a look.

Counting myself there would be five people.

Q. And prior to your testimony today did you list who those individuals were that performed some form of analysis or some step in the analysis to tell us what they did?

A. I did. I did. I prepared this in advance.

If I may stand up and flip the chart.

MR. BURGGRAAF: And with that, no further questions, Your Honor.

THE COURT: Thank you.

You may cross-examine.

MS. BECKETT: I have no questions for this witness, Your Honor.

THE COURT: Thank you, Ms. Beckett.

09:16:47 You may step down.

THE WITNESS: Thank you.

THE COURT: You may be excused.

And the government will call its next witness.

MR. BURGGRAAF: Your Honor, the government will 09:16:57 call Nicola Ranieri.

THE COURT: Come forward and be sworn, please, at the podium.

THE CLERK: Just right here. Just raise your right hand.

09:17:27 NICOLA RANIERI,

called as a witness at the request of Plaintiff,

having been first duly sworn, was examined

and testified as follows:

THE WITNESS: Yes, I do.

09:17:34 THE CLERK: If you'll just come around to the witness box here.

Please state your name and spell it for the record.

THE WITNESS: Nicola Ranieri. N-I-C-O-L-A, Ranieri, R-A-N-I-E-R-I.

09:18:06 THE COURT: You may proceed, Mr. Burggraaf.

DIRECT EXAMINATION

BY MR. BURGGRAAF:

Q. Mr. Ranieri, can you tell me what your current occupation is and who you work for?

09:18:13 A. Yes. My current occupation is a forensic scientist at the Food and Drug Administration Forensic Chemistry Center, which is a specialized laboratory that was forensic for the FDA.

Q. And throughout your testimony I may refer to that

09:18:35 as the FDA lab. How long have you been working at the FDA?

A. Quite a long time. I was essentially co-oped while I was going through my undergraduate at UC since August of 1989, so it was 30 years.

Q. And at the FDA lab what are your job

09:18:59 responsibilities?

A. Well, I'm a scientific, microscopist. I do various forensic related analyses. You know, tampering, counterfeiting and various other consumer complaint samples cases.

09:19:20 Q. And what's your education background?

A. I have an undergraduate degree from the University of Cincinnati, Bachelor of Science degree.

Q. And did it have a focus as far as your Bachelor of Science?

09:19:33 A. That's correct, yes. Biology.

Q. And do you have any additional training that relates to your current responsibilities?

A. Actually, yeah. I have quite a few, but over the years, you can imagine. So I've taken many courses. For specifically for this case I'm going to pick the ones that relate to this moment here. So I took a Confocal microscopy and image analysis at George Washington Medical School. I took a computer-assisted image analysis at North State University in North Carolina, State University, a computer-assisted image analysis at Rochester Institute of Technology.

I have had multiple others in the toolmark arena, such as Dayton Crime Laboratory toolmark analysis training. I had regional crime laboratory from Dayton in toolmark analysis. I had an ATF toolmark analysis training at the coroner's office in Cincinnati, Ohio. And I also have taken a tablet formulation and design in manufacturing tablets and tablet punches at the training facility in St. Louis, Missouri. I could go on.

Q. But you don't need to. You sound like you've had quite a bit of training.

A. Yes.

Q. Do you provide training or have you provided training to others in your field of expertise?

A. Yes. You know, there's many inference related, so

I'll pick a few again. One is the, it's a German name. I can't pronounce that one. So it's a Food and Drug Administration like agency. But it's a chemistry and physics in Vienna, Austria, analyst that came to our laboratory, and I trained him. There's the forensic science -- forensic chemistry scientists at the city of police in Taipei, Taiwan. Forensic science and physics laboratory from Singapore. These are agencies that do similar things that we do, and many other within the Food and Drug Administration and other agency like Food and Drug Administration nationally.

Q. Have you published articles or literature in areas of your expertise?

A. Yes. I published many. But for this particular one it would be, the most appropriate is the 2-D, 3-D examination of tablet formulations and for suspect counterfeiting and tablet sourcing. So that one's done at the microscopy microanalysis in 2010.

Q. And you actually hold a patent for some of what you do?

A. Yeah. I was lucky in my career because the laboratory started when I started back in 1989. So everything was new. So eventually I came up with a -- when you look at tablets and someone hands you a bag of tablets you have thousands of tablets. To look at them all it's not easy through a microscope. So eventually I came up with something

called alternate light source technology where essentially you spread out all of these tablets. You illuminate with a specific light in a wavelength whether it's UV visible and infrared, and then you can see the difference between a suspect generally.

09:23:54

Then I created -- with that knowledge I created a device that now today I have two full patents, one pending international and three European patents pending still on the device, and the FDA uses these device to detect or red flag a suspect.

09:24:17

Q. And have you testified as an expert before?

A. Yes.

Q. How many times?

A. Three. But specifically the one in this case last year was about three.

09:24:28

Q. And has the court ever made a finding that your testing methods or results were not accurate or correct?

A. I'm sorry. Could you repeat that?

Q. Has the Court ever made a finding that your testing methods or results were inaccurate?

09:24:44

A. No. No.

Q. Have you had training and experience in analyzing pill press punches and dies?

A. Yeah. As I stated earlier I took an actual course from a company called Natoli. They actually manufacture

09:24:57

presses and tool punches. And they actually have a facility that train you and whoever wants to be a tool press operator. So I took that course where that is, you know, the design that punches a design, the tablet formulation, and they show how to, train you how to run a press.

09:25:20

Q. And what did you do to prepare for your testimony today?

A. I reviewed the work I did when I actually did the work.

Q. How did you become involved in this case?

09:25:35

A. I received -- at our laboratory you have a lead analyst, and then you have everyone else that follows. A lead analyst is usually the analyst that receives the case. And in this situation Mr. Platek was the lead analyst in this particular case, so he did what we call a Section One. Section One is an overall over everything that he's received. Part of the supervisors and management of the laboratory is instructed to have this technique done. So I was one of those techniques that was supposed to analyze these tablets.

09:25:59

Q. So in your role in this case were you directed to analyze and compare the tablet punches embossed with GG249 comparing them to each other and to tablets that were debossed with GG249 in Items 14 through 19?

09:26:22

A. Could I ask you to repeat that? Sorry.

Q. Were you directed in this manner to analyze the

09:26:47

tablet the punches --

A. Yes.

Q. -- embossed with GG249?

A. Correct. Yes, I was.

09:26:55 Q. And compare them to each other?

A. Correct.

Q. And then compare them to the tablets or pills that were in Items 14 through 19?

A. Correct.

09:27:08 Q. Were you also directed to analyze the tablet punch tips embossed with an M and enclosed with a square comparing them with the tablets that were debossed in a like manner?

A. Correct.

Q. What process and equipment did you use to perform

09:27:21 your analysis?

A. The technique is called profilometry. In our laboratory we have an array of disciplines and instrumentations. When we have visitors usually these visitors go through all these techniques. And the microscopy

09:27:45 because it's visual as well as analytical is the most attractive. I wish I had a way to show you what a 3D image looks like, 3 dimensional image looks like. A system that is called IFM, Infinite Focus Microscope. What it does essentially is it scans. It measures the surface of a sample.

09:28:08 When it's finished collecting the whole surface it displays it

as an image, but it's really not an image because it has just data points.

Q. And did you use any other instrumentation or equipment in performing your analysis of the punch tips and the tablets such as 3DIA?

09:28:26

A. Yes. That instrument is called, we refer it to as 3DIA, which stands for 3-dimensional image analysis. It's considered a profilometer, so it was a technique called profilometry. The system, actually what it does is it collects -- if you envision a picture, just a picture, that's a flat image, so it's 2D. It's considered a 2D image. So you have an X and a Y that dictates where the point for that pixel. So, for example, X direction and a Y direction, then you find the two values and that's a point. That's a pixel.

09:28:53

In this case, the system creates X, Y and Z, which is the height. So you have two dimensional, and three dimensional makes the height.

09:29:17

Q. So talk to me about this 3DIA instrument. What is it composed of? What does it look like? And how does it operate?

09:29:42

A. It's a big microscope. It is a big microscope that has a precision movement stage. It moves in micrometer. Actually nanometer steps, and it has a sensor that illuminates the sample and collects, if you will, an image, but it's really data of the value of that XYZ point. The XYZ point in

09:30:05

particular for this case when it scans the whole surface, if you can envision X5Y10 and Z15, that's one data point. This collects 6.3 million pixels. To makes it easy, it's 6.3 million data points. So picture 6.3 million of those, and it takes those points and compares to a known would equal number of points, and it as an algorithm, and it calculates and XYZ location right here at this three-dimensional space. Does this unknown have this point right here? Yes or no? If it does, it's counts it as a yes, it has it. After 6.3 million points it gives you a percentage of how many of those points found the same at this from a known authentic to an unknown suspect.

Q. Let me see if I understand, if I can explain that correctly. Using this 3DIA equipment you can put a pill in front of the equipment and it's going to gather from the surface of that pill essentially 6.3 million data points?

A. That's correct.

Q. You can put another pill and get 6.3 data points that you can then compare those data points?

A. That is correct. Yes. So the beauty about this technology, this technique, this instrument is that it's extremely consistent. And prior to any analysis, this analysis or any analysis I've ever done with any technique really in this case with this 3DIA system we also measure also an authentic where we already know the data and results so we

can confirm that, yep, we got the same results as we got in 2010, 2015, last month.

So the tablet that it collects these points is then saved the data. It's called data set. Then we have a library of authentic. We call that up, data set, and we tell the system, okay, go ahead and compare these two data sets, and return a percentage.

Or there's another technique that's called profile measurements that actually gives you a cross section of that particular surface, and it compares if these two profiles line up exactly or not. If it doesn't, you'll be able to visually see it.

Q. So you can compare one pill to another. And when you reference authentics are you referring to official manufactured tablets from the official manufacturer?

A. That is correct. We -- because we do always a comparison with an authentic we always have to have authentic from a manufacturer. So if we don't have it, then we communicate -- well, myself, for example, I requested, through the proper channels I request an authentic so I can use it in my analyses. And then there's a special group that actually reaches out to the genuine makers, genuine makers of a particular product, and it requests as an FDA agency to send us some authentics. So it usually sends us a bottle of tablets or capsules.

So in this case we had all three already, and we had those in the library already. So that is the process, so comparing to what we call authentic. Also we consider that a known because we have a known value.

09:34:30 Q. Now, we talk about comparing pills to pills.

A. That's correct.

Q. Can you also use this 3DIA analysis to compare pills to punch press tips?

A. Yes. That's correct; because the system pretty

09:34:46 much can scan or measure anything you put underneath this. So in this case we can put the tablet punch under there, or we can create what is called casting using Mikrosil. And then we have the actual. Such a Mikrosil is a way to create the same surface as the punch tip that made a tablet. You take that

09:35:12 same punch tip. You put Mikrosil on the top. It's kind of like making an identical tablet that this punch tip will make. So then we compare the punch tip or the Mikrosil to a tablet.

Q. In this case, before you began your analysis in using via equipment did you verify that the equipment was

09:35:34 operating adequately?

A. Per our SOPs and per, you know, the laboratory you cannot proceed without what is called a verification to make sure that the system is running as it was yesterday.

Q. So you talk about these data sets and the potential

09:35:56 for at least in one aspect of it to collect 6.3 million data

points.

A. Correct.

Q. Am I correct in assuming that you're using the -- essentially the microscope is taking an image, but that's taking those data, that net data, and you're then using a computer to process that data?

A. Yes. It's a system. So the microscope is coupled, it's attached to a computer. The computer runs the microscope essentially. So the computer will collect the data that the sensor is picking up and transfers electronically obviously to a computer. The computer then converts that signal to a data point or data points, and it saves it. I'm prompted to save it or not, then I save the image. I hate to use the word image because it really isn't an image because you see it. It's really a wire frame of value points. It's not really an image, but to make it easy for humans they give you an image.

So it takes these points, then I call up the same software, call up the data set of the one that I just scanned, just measured, call up the data set file of the known or authentic or genuine. And the system has multiple ways of comparing. I pick what is called difference measurement analyses as well as profile management analyses.

Q. We'll maybe get to having you distinguish what each of those mean. Before we do did you document your findings after performing this analysis?

A. Yes. At the end of the process that the system is comparing it to it prompts to save a PDF file for the report, which is a report. Then we take those reports and pile them up, save them. And then you take -- after you finished collecting all of your items, tablets or punches or Mikrosil, and when the whole work is complete then you put this package together, which we call a section.

Q. Let's look at some of essentially your findings. If we can look at Government's Exhibit 24.09.

Am I accurate in stating this is a comparison photo of a tablet punch tip, a Mikrosil cast of a tablet punch tip from Item 22 to an actual tablet from Item 17? Is that correct?

A. Yes, that's correct.

Q. So tell me what we're looking at in this exhibit.

A. As mentioned, the image on the left, which is shiny, metallic looking, that is the tip what we call the tablet punch tip. That is the phase that actually comes in contact with the powder that eventually is pressed to make a tablet, so that's a punch tip.

The one in the middle essentially is a Mikrosil, a casting of that punch tip. Essentially is treated, the punch tip is treated with Mikrosil as if you were making a tablet. So instead of making a tablet you're making a casting which is similar to making a tablet. And the far right, the brownish

appearance, that's the tablet, Item 17, Tablet 1.

So looking at these three here put together, the reason this was put together is because through the process of tablet making just like any technique you have to essentially take care of your instrumentation. So the punch tip, it's a tool that makes the tablets. Therefore, if you don't take very good care of that damage occurs through changing, through replacement, through to a high pressure, anything that causes, in this case, there's a green arrow, that causes a dent. You can see the little dent on the bottom of the edge of the metallic looking punch tip. There's a green arrow pointing, as you can see it's over exposed only because, you know, it's shiny. But there is a tiny little bump as you see it coming inward. That's on the edge of the tablet punch tip cup. The cup is what essentially makes the shape.

On the center you have a Mikrosil with a green arrow also points to the same. As I explained it earlier the punch tip once it presses onto a powder to make a tablet it essentially transfers everything, every shape of it. In this case that little dent was transferred into the Mikrosil. If you see on the far right you see the same dent on the tablet that was pressed by that punch. Because of the location it's quite evident that that punch tip appears to have made that tablet.

And on the red arrows, I just wanted to bring that

point out. I can, can't I?

Q. Yes.

A. It's an important part because punch tips are made typically by what's called the master hub. Master hub is the master punch tip, and that's where all the other punch tips will be made. So when a manufacturer manufactures the punch tips and they make the master, consequently after that, they make other punches using this master. The master is made with high strength steel that is treated to be harder than a metal that they make for when you make a punch tip. So you take this master and it press it with extreme pressure and transfers what's on the hub onto another punch tip, so you created a punch tip.

The reason I'm explaining this is because the master hub, the design, the original punch tip, that punch tip, the punch tip makes all the other punches, it's called the hub. It's made with -- in this case you can see the lines, I don't know if you can see those lines. You know, forgive me about the compression of PDF, but it was quite clear on the actual image, those are called CNC process. That's process called computer numeric calculations. And that is what made the master hub.

So those lines are made through the process of making a hub, which then later the hub which is the master will press onto another softer metal to make the punch tips.

So that punch tip there with those lines and that arrow, you can see the casting Mikrosil in the center that shows the same centrifugal CNC lines, and you can also see them on the tablet.

09:44:06 Q. So can you use essentially a comparison of the defects or characteristics of a punch tip to determine whether a pill or tablet was made by that punch tip?

A. The process of making a tablet punch is revealing that the process that took place of making that punch tip. 09:44:35 When there is a damage or a dent or nick or burr on a punch tip it's kind of like creating its unique fingerprint.

So if I were to press my hand on here, take it off and it left a mark, that mark there is essentially my hand. If I cut myself and I press on it you're going to see the cut 09:45:01 there. So when there's a damage on a punch tip it will continue to replicate that on all the tablets that it makes.

Q. Okay. Let's go to Government's Exhibit 24.10. What are we looking at here?

A. This technique -- again, this is profilometry. And 09:45:29 this particular technique is called profile measurement. Please tell me if I need to move this closer. Profile measurement. Yes. The grey image on the upper left corner with the red band across it, that one there is a casting of the punch tip. The red band is what the system will take and 09:45:55 calculate a cross section of that line. On the right side of

the grey image is the profile, the cross section of that red band on that casting material. Beneath it below the grey image you have a brown, which is a tablet with the same red line going across it creating again its own profile.

09:46:29 You take the two profile diagrams on the right of the tablets, and the system is then, compares the two superimposed and overlays them together. And anything that overlays quite well tells you that it's a pretty good, pre-consistent to it to each other.

09:46:51 Q. The jury has heard prior testimony about these Mikrosil casts being made of the punch tips that were provided. They also heard testimony that the punch tips for this specific drug exhibit number was found on the floor of a bedroom in the defendant's home. That would be Item 20. It

09:47:18 appears that Item 14 as you stated was one of the Alprazolam pills that was analyzed; is that right?

A. That's correct.

Q. And the jury heard prior testimony that Item 14 had a specific DEA exhibit number which correlated it to prior

09:47:36 testimony of a pill that was seized from codefendants Tonge and Bustin in November of 2016. With what we are seeing here on the comparison of these two times what can we conclude as far as the punch tip from the defendant's home and the pill that came from a codefendants' home?

09:48:02 A. What I can conclude is that the two are consistent

to each other.

Q. Let's go to Page 2 of this exhibit.

Now I made a mistake of leaving out a page which deals with if I remember difference measurement analysis.

09:48:19 A. That's correct.

Q. Why don't you explain what difference measurement analysis is.

A. Just what I'm seeing here is a half page. Is that what I'm supposed to see?

09:48:33 Yeah. Thank you. Okay. So this is the second page of essentially describing what the system did prior to this. The difference measurement module, which again, is a different technique than the profile measurement module. The difference between the two is, one, as I mentioned, one

09:48:58 creates a cross section of my hand so you can compare the two, the line and gives me a line so you can compare that line; the other one, the difference measurement, in this particular case this is a difference measurement, it takes the tablet and it essentially measures every parts of that tablet. Again,

09:49:19 repeating it again, but it is what it is, 6.3 million XYZ locations points. That is it.

These points are then calculated, the algorithm calculates between what we just saw, the grey casting and the tablet and gives how many -- what is the percentage of the

09:49:46 same exact location that the system saw? 6.3 million points

of XYZ locations, 97 percent and slightly higher than that were in the same location, which that translates to they're consistent, very consistent to each other.

Q. Does that mean that it is pretty likely that the punch tip analyzed created the pill analyzed?

09:50:10

A. Yes, correct.

Q. Let's look at Exhibit 24.11. Can you explain what we're looking at here?

A. Yeah. This is -- okay. Obviously these are

09:50:32

punches, and this is a good example of what we talked about just a bit ago about creating its own individual fingerprints. In this particular case the images that are labeled A and the center one B and the one to the right C, they're all showing what in this discipline is called sticking, picking and

09:51:02

sticking. Sticking and picking. And it is exactly that. It is material sticking to the punch face to the punch tip. And that is a lot of times is due to poor maintenance of the tool.

For example, one of the things that one could do to avoid material sticking as you can see on image B, underneath

09:51:33

it shows up close the 9, there is a type material that is stuck to it. That type of material is essentially for as long as it's on there it will create its own additional fingerprint to whatever it stamps, whatever tablets it makes.

So this really happens when -- for example, you

09:52:00

wouldn't drive a car 100,000 without changing your oil. You

have to do some cleaning. You have to maintain it. So maintaining your tools is your livelihood. So without doing cleaning, often cleaning this can happen. There are other reasons that it can happen, but this is typical of potentially
09:52:30 low maintenance. And when you do low maintenance on these tools it stays, that material stays on there for as long as it's able to adhere to it.

The one on the C shows a lot more material stuck to it. And that is actually going to be transferred on tablets.
09:52:57 The A was rather clean. There was nothing sticking to it. So that one there will create an exact image or a higher quality image when you compare it to a casting with the Mikrosil because it's nice and clean. The one further to the right, the C or the B, those have additional variations to
09:53:23 fingerprints such as material stuck to it.

Q. So if there was a punch tip that has some sticking and picking, it's going to carry over the defect to the pills that it punches and are created.

A. That's correct. A lot of times that happens when
09:53:43 in the tableting production, manufacturing, you have essentially what is called cohesiveness forces and adhesive forces. So when the packing, the pressure to make a tablet, the cohesiveness of the formulation, if it's not as strong as the adhesiveness of the cup essentially being more attractive
09:54:14 to it material will come off and will stay to it. So a lot of

that happens when again maintaining the tools, adding lubricant to the formulation, things like that.

Q. We are going to look at some more comparisons that you made between Mikrosil cast of the punch tips and pills seized in this case. The jury has previously heard that prior to creating those Mikrosil casts that Mr. Platek actually cleaned them off. When we're looking at that percentage in comparison, if the picking and sticking is removed is that going to cause a difference in that percentage?

09:55:00 A. Correct. Yes. Correct. And I believe I do have some data to show where the picking may have been. So, yes, correct.

Q. Let's go on to Exhibit 24.12. Why don't you tell us what we're looking at here. It looks like a similar

09:55:22 comparison, but this time from Item 14. Again, an Alprazolam pill that was seized from the Tonge/Bustin home to what the jury has heard testimony about, an Alprazolam pill that was seized from a net basket in the defendant's basement. Tell me in comparing those what are we looking at here?

09:55:45 A. Okay. What you're seeing is the profile measurement. In this profile measurement you have two tablets that is actually a 3D image converted into a JPEG. But each of these tablets with the red band I described earlier creates a diagram. So tablet -- I'm sorry. Item 14, tablet 3, here's

09:56:15 the diagram on the right side. Item 18, tablet 1, the diagram

is on the right side. The beauty about this particular one is the debossing was nice and clean. Therefore, they're practically indistinguishable because there was no unique individual fingerprint due to sticking and picking.

09:56:42 Q. Let's look at Page 2 of the same exhibit, if you can zoom out.

Explain this aspect of your analysis on comparing these two pills.

A. So. Yes, thank you for zooming in. So here this 09:56:58 is the difference measurement module. Again this will take one tablet and measure every component of that, every part of that surface to every other part of the other surface and look for the XYZ 6.3 million points and comes back with a result that says how many at this point in this percentage map the 09:57:29 same location? In this particular case as you can see it was very little sticking in there, so the percentage is quite high.

Q. Is it fair to say that based on your analysis that each of these pills that came from different locations were 09:57:44 actually made from the same punch tip?

A. Yes. Based on the analysis that we do authentics to authentics, when you see numbers like this they do come from the same place.

Q. Let's look at Exhibit 14. And you've given quite a 09:58:05 bit of explanation as to how to more or less compare or how

these are compared. This appears to be a tablet from Item 14, which the jury heard testimony came from the Tonge/Bustin home, to Item 19, which was seized by postal inspectors according to prior testimony. Are these essentially Alprazolam pills that were likely to have been made by the same punch tip?

09:58:31

A. Based on the comparison with the casting, yes, they're very consistent.

Q. Let's look at Page 2 of this exhibit, as well, if you'll zoom out.

09:58:47

Again, like the prior exhibit, it looks like there's a high percentage of those 6.3 million data set, there's a high percentage of them being exactly aligned with each other; is that right?

A. Correct.

09:59:02

Q. Let's go to Exhibit 24-14. Again, looking at a similar diagram but comparing a punch tip which the jury heard testimony was found on the floor of the defendant's home to what appears to be an authentic Alprazolam pill; is that right?

09:59:28

A. Correct.

Q. And how did the punch tip compare to an authentic?

A. As you can see the two diagrams related at the bottom, they have very little resemblance to each other, not consistent with each other.

09:59:44

Q. And let's look at Page 2. And what would we conclude from the information here?

A. That the lower percentage such as that one there are quite a few XYZ locations that are not the same location as the comparing sample.

Q. Let's look at the next exhibit, 24.15. This appears to be a comparison of a Mikrosil cast of one of the punch tips for an M box or Oxycodone punch tip. The jury heard testimony that items for this exhibit actually came from a pill press from Mr. Shamo's home on Titian Way that actually is compared to a tablet in Item 8, which is a tablet that came from the Tonge/Bustin home. What can we conclude from what we're looking at here?

A. Once again, the two diagrams are overlaid at the bottom. While they may not be over top of each other as the previous there's a lot of sticking and picking going on in that particular tablet. They're very consistently consistent to each other.

Q. The sticking and picking that may have gone on in the creation of that tablet, can the mere fact that the punch tip being cleaned prior to creating the Mikrosil casts account for some of the difference?

A. I'm sorry. Could you repeat that?

Q. So as the jury heard in prior testimony that the punch tips were, any debris was cleared off of them --

A. Correct.

Q. -- creating the Mikrosil cast. Can the fact that some of that debris being cleared off prior to creating the cast account for some of the difference between the Mikrosil and the actual tablet?

10:01:47

A. Correct. That is typical when you remove material from such sticking and picking. But the overall shape as you can see is quite consistent.

Q. Let's look at Page 2 of this exhibit. What can we conclude from in information?

10:02:10

A. Once again, is not as high as the 99 percent, but it is quite close. The XYZ locations were quite consistent to each other in the 6.3 million points there. So this was very consistent to each other.

Q. The defendant has been charged in part for pills, the possession of pills at locations other than his own home. If the punch tip came from his own home and these pills came from another home, what's the likelihood that the pills were originally made by that punch tip in the defendant's home?

10:02:32

10:02:55

A. Quite high.

Q. Okay. Let's go to 24.16. Here it looks like it's noted that we're making or you're making a comparison of a Mikrosil cast of a punch tip of an M box or Oxycodone punch tip. The jury heard testimony related to the DEA drug exhibit number that this came from Mr. Shamo's home on Titian Way, the

10:03:23

punch tip did. And it looks like it's being made -- or compared to a specific suspect pill that is in Item 12 that was also seized from Mr. Shamo's home. What can we conclude from your analysis depicted here?

10:03:45 A. That they are consistent with each other.

Q. And let's look at Page 2. Can a similar conclusion be made based on the information we're seeing here?

A. Yes, correct.

Q. Let's look at Exhibit 24.17. And I promise not to

10:04:10 belabor this any longer past this. What are we looking at here?

A. This is actually really is my favorite type of analysis because here the colorful little area there is to describe what really, you know, sticking and picking is doing

10:04:32 to the fingerprint of this. The arrow, you know, that's pointing to the diagram will show why that -- yes, beautiful, thank you. The tips are gone. You know, if you see, for example, the bump, on the left side there's a bump and going down and back another bump, the one on the right, there's

10:05:00 quite of material missing. If we zoom out, a similar situation is at the bottom showing what's missing there. So you have the little bump in the diagram. So this was a way to describe why you see some areas that don't, they do not have right on top of each other. So that is due to sticking and

10:05:25 picking.

Q. So it looks like you have a red arrow on the second diagram towards the top. Is that what's depicting then, that as well as the other depicting where there's --

A. There's picking all over there, yeah.

10:05:41 Q. And the jury previously heard testimony that linked the DEA exhibit from Item 21 to a pill press in Mr. Shamo's home that's stated previously with the suspect pill Item 13 coming from a DEA exhibit that was seized by postal inspectors.

10:06:04 While we have some what you explained as picking and sticking with the suspect pill, what conclusion can we reach even with that picking and sticking?

A. That this is consistent with each other.

Q. I want to pull up side by side if we can.

10:06:24 THE COURT: I assume you've got -- Mr. Burggraaf, I assume you've still got some time about this witness.

MR. BURGGRAAF: In fact, I'm on my last probably three or four questions.

THE COURT: Oh, all right.

10:06:37 MR. BURGGRAAF: If I may. If we can pull up alongside what we're looking at here, the photo 24.05.

Q. BY MR. BURGGRAAF: You mentioned previously picking and sticking. Is photo 24.05 an example of picking and sticking?

10:07:02 A. An excellent example of picking and sticking.

Q. The difference that's shown between the Mikrosil cast in 24.17 as compared to the pill, is that possibly due because the picking and sticking was cleaned off of this punch tip before making the Mikrosil cast?

10:07:21 A. Correct.

Q. And based on your -- actually if we can go back to 24.17 by itself, and look at Page 2.

And based on the information here as well as the analysis you did on the prior page is it fair to conclude that

10:07:55 the punch tip that was found in Mr. Shamo's home was very likely to have created the pill that was seized by the postal inspectors?

A. Correct.

MR. BURGGRAAF: No further questions.

10:08:07 THE COURT: How much time do you think you need for cross?

MR. SAM: I don't have any questions, Your Honor.

THE COURT: Thank you. You may step down and be excused.

10:08:19 We'll take our first break.

(Whereupon, the jury left the court proceedings.)

THE COURT: Let me talk to your lawyers for a minute. Others of you can go or come or sit or do whatever you want.

10:09:03 I read your government's paper this morning. You

did not, the defense did not designate a medical expert to opine on defendant's, any diagnosis of any particular malady; is that correct? It is my understanding; correct?

MR. SKORDAS: Yes.

10:09:23 THE COURT: And I take it you're not intending to designate one?

MR. SKORDAS: That's also correct.

THE COURT: Nonmedical expert -- nonmedical people can't testify as to a diagnosis.

10:09:36 MR. SKORDAS: Right.

THE COURT: I mean, they can testify as to -- they can't say somebody has X, Y or Z. They can give their observations about things that are common that we all make observations about, intelligence, ability to organize, certain

10:09:53 behaviors and all that.

But so I don't think there's really an issue there, is there, having clarified that? You're not intending to try to get an expert designation now?

MR. SKORDAS: Nope. And we don't intend to use

10:10:06 those witnesses as experts for the purposes of any medical diagnosis.

THE COURT: Mr. Gadd?

MR. GADD: I just want to make sure we're all clear. So in the opening it seemed pretty clear to me as I

10:10:21 reread it that was the intention for those witnesses. It's no

longer the intention? Or maybe it never was.

MR. SKORDAS: They can talk about his -- I mean, it's his mother, Your Honor. She can talk about his growing up, his perhaps learning disabilities, other things that happened, not as an expert, but she would know as well as anyone else about those things. And we can address those through factual questions and avoid anything that appears to be an opinion.

THE COURT: She can do that.

MR. GADD: Learning disabilities is a diagnosis. ADHD is a diagnosis.

THE COURT: ADHD is clearly a diagnosis. I guess she can testify about things that she observed that perhaps she thought were learning disabilities without learning a diagnosis.

MR. SKORDAS: That's all we intend to do.

THE COURT: That's fairly common.

MR. GADD: Sure. I think he indicates that it might be factual, not opinion. I think it is opinion, though; right? Isn't she going to give her opinion that perhaps, and I don't want to put words in her mouth, but perhaps in her opinion her son didn't or wasn't smart, you know, things of that nature? I think it is opinions.

THE COURT: Well, every mother has opinions about whether their kids are smart or not.

MR. GADD: Sure.

MR. SKORDAS: They're appropriate lay opinion, Your Honor.

THE COURT: Some things are appropriate opinions given by lay people, particularly lay people who know people well.

MR. GADD: Yes, sir. I think those type of opinions come in under 701. But what I worry about is testimony such as, we took him to the doctor, and he got a diagnosis and here it is. Or --

THE COURT: No. I'm not going to permit that.

MR. SKORDAS: Nor do we have any intention of doing that.

MR. GADD: Okay. Thank you, Your Honor.

THE COURT: Thank you. We'll be in recess for about 20 minutes.

(Recess.)

THE COURT: Do you have your next witness?

MR. STEJSKAL: Yes.

THE COURT: Let's get the jury.

(Whereupon, the jury returned to the court proceedings.)

THE COURT: United States may call its next witness.

MR. BURGGRAAF: United States calls Dr. Adam

Lanzarotta.

THE COURT: Come forward and be sworn, please, at the microphone.

THE CLERK: Just right here. Please raise your right hand.

ADAM LANZAROTTA,

called as a witness at the request of Plaintiff, having been first duly sworn, was examined and testified as follows:

THE WITNESS: I do.

THE CLERK: Please come around to the witness box. Please state your name and spell it for the record.

THE WITNESS: Adam Lanzarotta. A-D-A-M, L-A-N-Z-A-R-O-T-T-A.

THE COURT: You may proceed, Mr. Burggraaf.

DIRECT EXAMINATION

BY MR. BURGGRAAF:

Q. Dr. Lanzarotta, thanks for being here today. Can you tell us what your current occupation is and employer?

A. I am a chemist for the Food and Drug Administration's forensic chemistry center.

Q. And for simplicity throughout your testimony I'm going to refer to it as the FDA lab.

A. Sure.

Q. Can you tell me how long you've been with the FDA?

A. 11 years.

Q. And what are your responsibilities in your position?

A. I am a chemist, so we examine compromised FDA regulated products for tampering, adulterations, counterfeiting, diversion, things of that nature.

Q. You mentioned adulteration. What do you mean by that?

A. Products that may have ingredients in them that shouldn't have.

Q. And what's your education background?

A. I have a Bachelor of Science in Forensic Science and Ph.D. in chemistry.

Q. And what training -- other than your education what other training do you have related to your position at the FDA?

A. I've taken a few courses specific to my particular field of expertise at external -- with external outside FDA and also internal FDA courses. And I've also instructed many courses, as well.

Q. What type of courses have you instructed?

A. Specific to my field. So once we get into a little bit later when we get into exactly what my field of expertise is specifically, infrared spectroscopy. I've done a lot of courses in that area.

Q. The infrared spectroscopy, is there an abbreviation for that?

A. Sure. FTIR, and that is fourier-transform infrared.

10:38:04 Q. FTIR. I'm going to use that, as well, because I most definitely would mispronounce it.

A. Sure.

Q. Do you have any publications in your expertise?

A. Sure. I have several.

10:38:16 Q. Do you want to provide an example of one are two of those?

A. Yeah. I've looked at a couple cases, counterfeit tablet cases, so I've done some investigating in that. Also in adulterated products, products like capsules and tablets

10:38:34 that have ingredients that shouldn't be in there, and using novel techniques to examine those types of products.

Q. And then you published based on what you found?

A. That's correct.

Q. And have you testified as an expert before?

10:38:48 A. Yes.

Q. How many times?

A. I believe five or six.

Q. And has the court ever made a finding that your test methods or results were not accurate or correct?

10:38:56 A. No.

Q. Have you had training or experience in identifying and analyzing Oxycodone pills, Alprazolam pills and Fentanyl?

A. Yes.

Q. For today what did you do to prepare for your testimony?

A. I looked back at over my notes, what we would call bench notes or worksheets that we generated specific to this case.

Q. We heard prior testimony from your colleague Mr. Platek who explained that you performed two different forms of analysis on items received by the lab, specifically alternative light source and FTIR, the infrared. As far as the alternative light source did you make any significant findings related to your analysis there?

A. No.

Q. Moving on to the FTIR, can you explain what type of analysis that is and the equipment that you use?

A. Sure. So it's a piece of equipment about this big, 2 feet, maybe, by about 2 feet deep, maybe, 8 inches tall, and it has a small aperture on it where we take a portion of our sample and put it on the aperture. And then we lower a pressure arm on top of that to make a compressed pellet.

And the way the instrument works is we pass infrared light through that window which is made out of diamond. The light passes through that small amount of sample

and then gets directed back towards the detector. And based on which wavelengths of infrared light that the sample absorb we're able to determine a chemical fingerprint for that particular substance.

10:40:48 Q. If I understand you correctly, then, the FTIR process does analysis of pills received, and you didn't necessarily do anything related to the punch tips that were received.

A. Correct.

10:41:00 Q. Your colleague, Mr. Platek, previously wrote down a list of categories of the items received by the lab. Does that look accurate as far as the first three rows for what analysis -- what items you did analysis on?

A. That's correct.

10:41:17 Q. I want to just confirm the type of tablets that you were dealing with. If we can go to Government's Exhibit 24.01. Do you recognize this photo?

A. I didn't take this photograph personally, but I do recognize it from the case.

10:41:40 Q. Is this one of the types of tablets that you performed an analysis on using FTIR?

A. Correct.

Q. And if we can go to 24.02. Prior testimony also provided to the jury that this was a photo taken in this case.

10:42:00 Did you perform analysis on this type of pill, as well?

A. Correct.

Q. And if we can go to 24.03. Again, prior testimony provided that this was one of the tablets that came in the items received by the FDA lab. Was this one of the types of pills that you performed analysis on?

A. Correct.

Q. Before utilizing the FTIR equipment did you do anything to verify that it was performing accurately and correctly?

A. Yes. Every day before we run any type of samples we have to do what is called a performance verification for each piece of equipment. And for this particular instrument we did that -- or I did that in this case.

Q. Previously the jury has heard testimony that several of the items listed came from specific locations significant in this case, specifically the defendant's home on Titian way, the Tonge/Bustin home in South Jordan and blue postal bin, which those items were seized by a postal inspector. They've also heard that some these drug exhibits tested positive for either Fentanyl or Alprazolam. Did you take any specific precautions in dealing with these items?

A. Sure. We have a safety procedure in our laboratory, general safety procedure. So we used personal protective equipment, gloves, glasses, laboratory coats. We conduct any type of analysis that we can inside of a

ventilation hood. And in the event that we don't have that capability we do have ventilation snorkels where we can actually move those over the piece of equipment that I use, and I can work my hands underneath that snorkel and take the portion of the sample, put it on the aperture, and it provides me with a barrier between the sample and myself. And then if there's anything that becomes airborne that ventilation hood will pick that up.

Q. And in regards to the 19 items, did you perform this analysis using FTIR on all at least one pill from all 19 items?

A. That's correct.

Q. And why did you -- or did you perform that test a single time? Multiple times?

A. I'm not entirely sure without looking directly at my notes. But I probably looked at it once.

Q. Okay. And can you describe what the portion of the pill it is that you actually performed an analysis on?

A. Yes. Typically in this case I'll take a tablet and I'll break it in half, and then I'll scrape a portion of the core of the tablet, so the inside of the tablet, onto the aperture of the instrument.

Q. And in your analysis did you compare the results of the FTIR of the suspect pills with authentic Oxycodone or Alprazolam pills?

A. That's correct.

Q. And how do you document your findings after your analysis?

A. Well, once we've run the sample we end up with what's called a spectrum, so it's just an XY plot, a graph, and on that graph is a fingerprint of that particular sample. So we compare the fingerprint of the suspect sample to the fingerprint of an authentic sample. And what we would do is provide that data as a printout and then compare those fingerprints to each other to make a determination on if the suspect sample is consist with the authentic or not.

Q. I'd like to look at some of that data that you gathered for your analysis. If we can look at Government's Exhibit 24.08. This is an FTIR result that -- or findings that you created; is that right?

A. That's correct.

Q. It appears that there are four boxes on this exhibit. Can you walk me through each of those boxes and what it is that we're looking at?

A. Sure. So if we start in the top left what we have here is the signature of each of the labeled items that I was talking about. So we have an XY plot. On the X axis or horizontal axis that's what wavelength we're looking at. And along the Y axis we're looking at the intensity or absorbance that we're seeing of each wavelength.

So if you look at the fingerprint, say, at the top example, Item 14, we get a signature or fingerprint. That fingerprint is consistent with each of the other items in this window here.

10:47:16 Q. So if the jury having heard prior testimony that each of the drug exhibits from which these items were taken from came from different locations, can you draw any sort of conclusion based on what we're looking at here?

A. The conclusion I would draw is that the infrared 10:47:34 signature of each of these tablets from each of these items are consistent with each other.

Q. And if we can zoom out and go to the second box. What are we looking at here?

A. So the second box here is what is the result of a 10:47:52 library search of one of the representative signatures or fingerprints that we were looking at on the previous page. So if you look at the very top it says, search results for the number, Item 14. So what we did was we took the spectrum. We searched it against probably 55- to 60,000 signature 10:48:20 fingerprints in our library, and these are the best matches that the computer algorithm determined.

Q. So based on what we're looking at here you've got Row 3 and Row 4 that reference microcrystalline cellulose. How likely was it that there was microcrystalline cellulose in 10:48:44 Items 14 through 19?

A. I didn't document it on here what the ingredients were because the question was just to compare it to authentic. But I do want to point out that based on the data that I'm looking at here, the suspect sample does appear to contained some type of cellulose.

Q. Okay. If we can go to Box 3. What is being compared here?

A. So in Box 3 we have one of our representative spectra signatures from box Number 1, and we are comparing that fingerprint, that signature, to that of an authentic Alprazolam 2-milligram tablet core that was manufactured by Sandoz.

Q. And in your expert opinion, can you draw any conclusions in making the comparison of those two pills, an authentic versus a suspect pill?

A. Sure. I can tell if you look at the peak positions along the X axis the signature of the suspect sample is not consistent with that of the authentic.

Q. And if we can go to the last box. I believe you've kind of summarized more or less your findings. Is there anything else noted here worth mentioning that you haven't already that you concluded?

A. I think this screen here summarizes everything.

Q. Okay. Thank you. If we can now go to Government's Exhibit 24.06. Noting a pattern here as to how these are

structured we may skip Box 4 because I'm going to anticipating you're going to explain to us what your conclusions are. We can look at Box 1. It appears from this that you're performing an analysis using FTIR for items that are scored as A215s; is that correct?

10:50:47

A. That's correct.

Q. And tell me the results of your analysis comparing those pills.

A. The fingerprint of each of these tablet cores were consistent with each other for each of the items listed in this window here.

10:51:02

Q. And if we can go to Box 3. What are we looking at here?

A. We're looking at the top representative spectrum from one of those that was shown in window Number 1 compared to the fingerprint of an authentic Oxycodone hydrochloride 30 milligram tablet core manufactured by Actavis. And what we can see here as in a similar situation as previously the signature of the suspect sample is not consistent with that of the authentic.

10:51:19

10:51:46

Q. And how -- do you have a reason for why or maybe visually is there something that tells you here as to why they're not consistent?

A. Yeah. If we look at the different regions down here, we see along the X axis the number 2000. So if we look

10:52:01

at everything to the right of that we see a different pattern of these peaks or these absorptions. And based on the differences in each of these peaks we are able to determine that the suspect and authentic are not consistent with each other.

10:52:23

We can also see in the authentic Oxycodone we have very sharp peaks around 17 -- between 1500 and 1800 that are characteristics of Oxycodone itself, the active ingredient. Those peaks are not present in the suspect signature.

10:52:44

Q. So if we can zoom out. What can you conclude, then, when comparing the suspect pills marked A215 to the authentic Oxycodone pill?

A. That the suspect samples were not consistent with the authentic.

10:53:05

Q. Were the suspect pills consistent with each other?

A. Yes.

Q. Okay. If we can move on to Exhibit 24.07. If we can zoom into Box 1. It appears that this is capturing your analysis results for the items provided the FDA lab that had a

10:53:35

embossment of an M with a box around it. Is that what that is?

A. Correct.

Q. And can you explain what we're looking at here?

A. Each of the signatures are, fingerprints here were

10:53:48

from each of the items that you have described that had or

consisted of a sample with an M30 stamp on it. And each of the spectra signatures, fingerprints of each of those tablets are all consistent with each other.

Q. And if we can go to Box 3. What are we looking at here?

A. We have one representative signature fingerprint from the box Number 1, and it is compared to an authentic Oxycodone 30 milligram core manufactured by Mallinckrodt, and the suspect fingerprint is not consistent with that of the authentic.

Q. So if we can zoom out. Is it fair to say that essentially regardless of the location of where these suspecting pills came from all of the suspect pills are consistent with each other?

A. Correct. Using this technique, that's correct.

Q. But they're inconsistent with authentic Oxycodone?

A. That's correct.

Q. If all the A215 and M30 suspect Oxycodone pills analyzed were found to be consistent with each other but also found not consistent with authentic Oxycodone pills, based on your training and experience what would you conclude?

A. Could you repeat the question? I'm sorry.

Q. It might have been a lengthy question. Let me rephrase it.

Is it probable based on your findings that all the

A215 pills would likely have come from the same source based that they're consistent?

A. I would say it's possible. There are other techniques that are more conclusive for that type of conclusion. And I think Mr. Ranieri's technique that he described would probably be the most appropriate to make that type of conclusion.

Q. Okay. Thank you.

No further questions.

10:55:52 THE COURT: Cross-examine?

MR. SKORDAS: No questions, Your Honor. Thank you.

THE COURT: Thank you. You may step down. And you're excused if you want to be.

The government may call its next witness.

10:56:02 MR. BURGGRAAF: The United States would call Heather McCauley.

THE COURT: Come forward and be sworn, please. Now you can come forward and be sworn.

THE CLERK: Please raise your right hand.

10:57:06 HEATHER ANNE McCAULEY,

called as a witness at the request of Plaintiff,

having been first duly sworn, was examined

and testified as follows:

THE WITNESS: I do.

10:57:11 THE CLERK: Please come around to the witness box.

Please state your name and spell it for the record.

THE WITNESS: Heather Anne McCauley, H-E-A-T-H-E-R A-N-N-E, M-C-C-A-U-L-E-Y.

DIRECT EXAMINATION

10:57:43 BY MR. BURGGRAAF:

Q. Ms. McCauley, thanks for being here today. Can you tell me what your current occupation is and where you're employed?

A. Sure. I am currently the director of

10:57:57 investigations in Cincinnati, Ohio, in the office of Human Animal Food. And we do inspections for human and animal food manufacturers in the state of Ohio and Kentucky. But before that I was a chemist in the forensic center for almost 26 years.

10:58:20 Q. And for use of reference I'm going to refer to that as the FDA lab. You say you were employed in there for about 20 years?

A. I was in the lab for about 26 years. I've been in my current position for about a year.

10:58:33 Q. What's your education and background?

A. I have a bachelor's of Chemistry -- I'm sorry. Bachelor of Science in Chemistry and in Biology.

Q. And when you're employed by the FDA lab what were your job responsibilities?

10:58:47 A. I would analyze evidence that was sent to the

laboratory for analysis, talk to Office of Criminal Investigation agents, write reports, review reports, write standard operating procedures and review them, maintain instruments, do verification of those instruments and make sure they were running properly.

Q. And what training have you received in addition to your education related to your FDA lab position?

A. Earlier on in my career I attended a mass spectra interpretation theory class. Also when we get new instrumentations in the laboratory usually we get some type of training from the manufacturer on how to use that equipment, and the FDA itself has various courses that you can take.

Q. And do you have any publications related to your job responsibilities that you had at the FDA lab?

A. Sure. I've given presentations and publications. I've given presentation at the conference on small molecule science on analyzing and identifying pharmaceuticals; a presentation at the American Academy of Forensic Science on the presence of pharmaceuticals and dietary supplement. I coauthored a paper with Dr. Lanzarotta, The Analysis of Pharmaceuticals, on a piece of equipment that was a combination of fourier-transform infrared and gas chromatography with mass spectrometry.

Q. That last one, we're going to talk about that some more.

A. Yes.

Q. Because you said it you saved me from saying it. Can I abbreviate it from here on out as GCMS?

A. Yes.

11:00:49 Q. The jury has heard prior testimony about GCMS, and I suspect that they may be somewhat of an expert at the end of the trial themselves. They might put some of you out of work. That being said, can you describe what GCMS is?

A. Sure. So again GCMS stands for gas chromatography

11:01:12 mass spectrometry. And so the instrument itself for visual purposes, if you can imagine basically a 3-by-3 box that sits on a benchtop. It's pretty unimpressive looking at it from the outside, but the magic happens on the inside. And so the gas chromatography part of that is if you can imagine like a

11:01:42 coffee stirrer that's 100-feet long and it's circled upon itself like a coil about 12 inches in diameter. And if you can also imagine that that coffee stirrer had a coating of material on the inside surface of it. So it's open, and stuff can pass through it, but there's a coating on the inside.

11:02:07 So what you do is you take your material, whatever you're trying to analyze, and you mix it with some type of a liquid. And you take that liquid, and you pull it up into a syringe and you inject it into the instrument through a port. And that port is about 500 degrees Farenheit. So it turns

11:02:29 everything into a gas.

And that gas then flows through that coffee stirrer, which is called a column. And that gas interacts or interfaces with the material that's lined on the inside of the coffee stirrer, if you will. And as it interacts with that
11:02:53 phase, what's called a phase, it separates out that mixture into its components.

So if you imagine like, say, a multivitamin. As those vitamins would be traveling through that column they interact with it at different -- like in different ways that
11:03:17 gives it separation. So say a Vitamin C might come out first, Vitamin A might come out next, Vitamin B will come out last. So you get separation in that way. That's what the whole purpose of gas chromatography is is to take a mixture, pass it through a medium and separate it into its components.

11:03:40 So once that happens and you have your individual components, they go into what's called the mass spectrometer. And at that point those individual components are hit with a voltage that explodes the molecule into a specific pattern, which is like a fingerprint. And that's how you can identify
11:04:04 what it is, because like that Vitamin C explodes the same way every time. It has a specific fingerprint that I can say that's Vitamin C. The same with Vitamin A, et cetera.

So then you get a piece of data in your computer that shows a graph with each of those individual components
11:04:29 making like a peak, and then you get also what's called the

mass spectrum, which is the fingerprint of each one of those peaks.

Q. Excellent. So there's essentially two processes that go on within the GCMS instrument.

11:04:45 A. Correct.

Q. Now I want to backup just a little. Have you testified as an expert before?

A. Yes.

Q. How many times?

11:04:52 A. 8 to 10.

Q. Has the court ever made a finding that your process or testing methods were not accurate or correct?

A. No.

Q. Do you have experience analyzing Oxycodone pills,

11:05:08 Alprazolam pills and Fentanyl?

A. Yes.

Q. So tell me how you became involved in this crime case.

A. My supervisor asked me to analyze the evidence that

11:05:19 I had submitted to the laboratory.

Q. And were you specifically directed to use the GCMS method for analysis?

A. Yes.

Q. And is the GCMS equipment and tool as well as just

11:05:36 the process generally widely accepted in the scientific

community?

A. Yes. And the technical -- the procedure that we use, I actually wrote that technical procedure and did the validation for it for a laboratory. And that's the general method that we use for GCMS analysis that come into our laboratory. And we have used that procedure on thousands and thousands of samples.

Q. Before using this box, the GCMS equipment, do you do anything to verify that it's operating correctly and will give you accurate results?

A. Yes. There's different types of verification. The one that's the most important for this analysis specifically is a daily verification where you run what's called a tune. And you're just making sure that the instrument is operating properly in the way that you expect it to on the day of use. We also have different procedures that we do that might be monthly or yearly to make sure that the instrument is in good operation and functioning the way it's supposed to be and well maintained.

And in addition to that when I run the samples themselves, the first time that I run them when I don't necessarily know what I have, I run what's called a screen check standard. And it has three known compounds in it that I'm looking to make sure that they're coming out and being separated the way that I mentioned. And in the mass spectrum

of them is exactly how I would anticipate them to be. So that's run with that set of analysis to ensure -- another safety to ensure that everything is going the way I would expect it to do that day.

11:07:30 Q. In your process when you're analyzing the substance you're actually taking additional steps to ensure the accuracy of the results such as doing multiple tests; is that right?

A. Yes. I run the standards in duplicate to make sure that the second time that I analyze it it looks exactly the

11:07:53 same as the first that I analyzed it. I also run certified standards.

Q. And what are those certified standards?

A. Well, it depends on the analysis that you're doing. So in this case the first time that I run the samples is what

11:08:09 I call the screen when I'm looking to see what I have. And then once I figure out what I think I have, which at that point I'm calling it a tentative identification. And then I'll run a second time with certified standards.

So in this case once I identified that I had the

11:08:33 active ingredients of Fentanyl and Alprazolam then I ran certified standards of those two compounds to show that what I see in the sample looks exactly the same as a standard of those materials.

Q. And how do you ensure that there's no cross

11:08:51 contamination between one test and another or no adulterants

when running this analysis?

A. Cross contamination between the samples?

Q. Between maybe from one test to the next. Does any material remain within the GCMS device between tests?

11:09:11 A. Generally no. But we run blank, what's called a blank. So in this case these samples were dissolved into methanol. And then I have a sequence that I run that I set up with each item in what order I'm going to run them in. And I run blanks in-between the samples to ensure that there's

11:09:35 nothing that's carrying over that would be showing up that shouldn't be there.

Occasionally if something happens that I would question that, I might -- the second time I run stuff I would change the order of the way that I run them so that they're

11:09:51 not run in the same order each time. So I do different things to ensure that I don't have that situation that you're describing.

Q. In this case did you only perform an analysis on the 19 items that contained different pills or tablets?

11:10:08 A. That's correct.

Q. And your colleague Mr. Platek on the paper to the left of you there categorized the first 19 items received into three different types of suspect pills or essentially pills with the same scoring on them. In looking at that, does that

11:10:29 accurately portray the categories and items that you did your

analysis on?

A. Yes.

Q. And was there a difference in results on any of the items that were scored with A215?

11:10:49 A. No. All of the A215s looked the same.

Q. And the next one down, Item 6, 8, 9, 10, 12, 13 scored with an M box and a 30, the results that you received was there any inconsistency amongst the items?

A. No.

11:11:10 Q. So each of the items are tested separately; correct?

A. Yes.

Q. So Items 14 through 19, did you find any inconsistencies in your ultimate results?

11:11:22 A. Within the Items 14 through 19 themselves, no, there was no inconsistencies.

Q. So let's talk about your results, then. After running the GCMS what did you find for Items 14 through 19?

A. Items 14 through 19 were Alprazolam.

11:11:41 Q. Okay. And for the items at the top that were the pills that were scored A215, what results did you find?

A. Fentanyl.

Q. And Items 6, 8, 9, 10, 12, 13 scored with an M box and 30 what results did you find?

11:12:01 A. Fentanyl.

Q. And you mentioned earlier that you at least run the analysis twice with the GCMS. The second time you ran it did it confirm the tentative results that you got the first time?

A. Yes.

11:12:18 MR. BURGGRAAF: If I can have one moment, Your Honor?

THE COURT: Yes.

(Time lapse.)

Q. BY MR. BURGGRAAF: I want to ask you, are you

11:12:31 familiar with the active ingredient in the authentic A215 tablets?

A. No; because I don't -- the purpose of my analysis wasn't to address authenticity. The purpose of my analysis was to simply look for any active pharmaceutical ingredients.

11:13:00 Q. And in performing your analysis were you asked to find the amount of the active ingredients?

A. No.

Q. Okay. No further questions.

THE COURT: Thank you.

11:13:11 Cross-examine?

MS. BECKETT: I have no questions for this witness, Your Honor.

THE COURT: Thank you.

You may step down, and you're excused if you want

11:13:20 to be.

THE WITNESS: Okay.

THE COURT: You may call the next witness.

MR. BURGGRAAF: The United States called Dr. Arthur Simone.

11:13:56 THE COURT: Come forward and be sworn, please.

MR. BURGGRAAF: If I can have a moment, Your Honor.

THE COURT: Yes, you may.

THE CLERK: Please raise your right hand.

ARTHUR SIMONE,

11:14:26 called as a witness at the request of Plaintiff, having been first duly sworn, was examined and testified as follows:

THE WITNESS: I do.

THE CLERK: Please come around to the witness box.

11:14:43 Please state your name and spell is it for the record.

THE WITNESS: Arthur Simone, A-R-T-H-U-R, S-I-M-O-N-E.

THE COURT: You may proceed, Mr. Burggraaf.

11:15:01 MR. BURGGRAAF: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. BURGGRAAF:

Q. Thank you, Dr. Simone, for being here this morning.

Can you tell me what your current occupation is and

11:15:10 where your employed?

A. I'm employed after Food and Drug Administration just outside of Washington DC. And I'm senior medical advisor in the office of unapproved drugs and labeling compliance.

Q. How long have you been with the FDA?

11:15:23 A. 17 years. Almost 17 1/2.

Q. And in your current role what are your responsibilities?

A. I work in the office of compliance, and our jobs are to make sure that the drugs that are available on the

11:15:39 marketplace are those that have been appropriately vetted by FDA, to be sure they're safe and effective and highest quality possible. And those that aren't are removed, and that's what my office does.

Q. Let me take you back 17 1/2 years ago. Where did

11:15:55 you work before the FDA?

A. Prior to FDA I was in private practice. I worked in the Philadelphia area. I was an assistant professor at the University of Pennsylvania for several years and then went on to several other colleges that were there. Hahnemann

11:16:13 University, Medical College of Pennsylvania and Drexel University as well as working in private practice.

Q. And what type of practice do you have?

A. Anesthesia.

Q. And what's your education background?

11:16:26 A. I started out wanting to be an engineer and got a

Bachelor of Science in Engineering Science, and then I went on to Penn State University at that point to get a master and Ph.D. in bioengineering. And my specialty there was gas mixing and aerodynamics and models of the upper airways and the lungs. And after that I went to medical school.

11:16:47

Q. And you passed?

A. Yes.

Q. You may have said it, just so I want to make sure I heard it, do you have a Ph.D.?

11:17:00

A. Yes, I do.

Q. What's the emphasis for that Ph.D?

A. It's bioengineering.

Q. Do you provide training instruction to others in your field?

11:17:10

A. At FDA?

Q. At FDA or elsewhere.

A. At FDA I do.

Q. What types of training do you provide?

A. For my first 14 years at FDA I worked in the office

11:17:26

of new drugs where we approved products, new drug products for anesthesia, critical care and in my case also counter terrorism. So I trained people how to do the review work from the clinical side, how to look at the clinical trials that were conducted, how to look at toxicology studies that had

11:17:46

been performed, how to reviewed chemistry manufacturing

control data in an effort to decide whether the benefit of a new drug outweighed its risk, and also look at the label and to make sure the labeling adequately informed a physician how to use a new drug.

11:18:02 Q. You mentioned you're evolved with new drugs applications and teaching others about that process. We'll come back to that. But do you have any publications or have you authored any literature related to your profession?

A. I have.

11:18:16 Q. What type -- can you give us a couple of examples of your types of publications?

A. Sure. One of the big issues that has occurred in recent years was whether anesthesia drugs affect the development of the brains of infants over the last trimester 11:18:36 of pregnancy and during the first couple years after birth while the brain is going through a rapid development phase. And we have done in work in that, especially with animals. And in the indication there is a lot of anesthesia drugs can affect the brain adversely and those affects can last 11:18:54 throughout life.

Q. And have you testified as an expert before?

A. I have.

Q. How many times?

A. Eight times.

11:19:00 Q. And has a court ever found that your testimony was

inaccurate or not correct?

A. No.

Q. What training or experience do you have related to Fentanyl and Oxycodone?

11:19:15 A. For the first 14 years at FDA I was oftentimes the only anesthesiologist in my division, so I covered all the anesthesia products, and that included all the intravenous formulations of Fentanyl. It's the newer versions of Fentanyl that came on the marketplace, I would be responsible for 11:19:38 reviewing those. And for older versions that had been out there for a while I would continue monitoring the safety of those and any changes and indications that the companies would seek.

Q. For the jury why don't you explain what is 11:19:51 Fentanyl?

A. Fentanyl is a potent opioid analgesic. It's a very strong painkiller. It's commonly used in anesthesia and sometimes in the ICU afterward.

Q. What did you do to prepare for your testimony 11:20:05 today?

A. I've had discussions with you about my knowledge regarding Fentanyl and anesthesia in general, and I've just reviewed some of the approvals of products that have been involved in Fentanyl.

11:20:22 Q. More generally, what does the FDA consider and

approve when an application is submitted as it relates to a controlled substance?

A. Can you rephrase that?

Q. What's the FDA's role in respect to controlled substances that want to be entered into the marketplace?

A. It would actually be treated the same as any other prescription drug product. The company that wanted to market these products would have to come to us and follow all the steps that are normally required to show that whatever its intended use is going to be and whatever the dose is going to be administered that the product is effective. It does what they claim it will do, and that the risks have been well established to the point where we can determine whether the benefits of the drug outweigh the risk or the intended use.

Q. So is what you just described part of the new drug application?

A. Yes.

Q. Are there any other significant parts of that new drug application?

A. Yes. So the drug application from very high level includes three things -- or four things, I should say. First is chemistry manufacturing and controls. So that's how the company is going to make the product. It has to be of the highest quality possible to minimize risk. So that includes everything from where they are getting their supplies, their

active ingredients, which is the ingredient that does the work of the drug, their inactive ingredients, how they're going to analyze the ingredients when they get them, when you buy from someone who sells them and then you have to also confirm what it says it has, and that it's the purity it's supposed to have.

It includes the recipe for how they actually go about making the drugs and equipment they use. It includes all of the specifications for the drug when it's completed and it's in its final format and how they go ahead and test that. It includes having to reserve the products so if there's ever an issue with it they can reanalyze it or give samples. And it includes an inspection to make sure that the facility really has the equipment they claim they have to do all this work. And that the facility is clean enough, if you will, that it's suitable for making drugs, especially injectable drugs. That's one section of the NDA.

Q. Thank you. When you were involved with new drug applications did you actually ever go and do the onsite monitoring yourself?

A. For inspection, no.

Q. Those who did go and do the onsite and monitoring and inspection would they bring back issues or concerns for you to give an opinion?

A. Yes. They would if they found something.

Q. I want to give you the opportunity to weigh in similarly today. I'd like us to look at Exhibit 13.09, Photo 10.

We're looking at photos of the defendant's home on Titian Way back in 2016. And I'd like to walk you through a room for which the jury heard prior testimony about, and similar to what you've done in your profession ask you what concerns or issues may arise were this the location being considered for approval in a new drug application. So do you have anything you could speak to as far as what we're looking at here?

A. Just based on a quick glance at the image, one of the concerns is the dust that's on the walls. I'm not sure what all the equipment is and whether it's all intact or not, but there appears to be the one container right in the center of the image where there's some white substance that's in there that's being exposed to the rest of the environment.

Q. And why is that -- why is the dust on the wall and the exposed material, why is that of concern?

A. There's two concerns. It depends on what the substances are in both places. But you can have the stuff on the wall get into the ingredients going into the drug product and vice versa. Stuff coming out of that container puts people at risk for inhaling it. And if that's what's on the wall it's a substantial amount. And on the other hand, dust

from the wall or anywhere else in the room for that matter that gets into that hopper looking device into the medication or the drug can cause harm to whoever takes it.

Q. And if we can move to the next photo.

11:25:11 Is this indicative of a standard location that would be approved for a pharmaceutical production operation?

A. No.

Q. And why not?

A. It's a very makeshift looking facility. It's not

11:25:34 something that appears to be permanent. With the purposes of the Bell jars that are lined up on the tables, I'm not sure -- the blockage of the windows with those pillow-like devices and a roll of toilet paper is something that you wouldn't normally see in a facility used by a company like Pfizer. And again,

11:25:57 you've got the dust on the walls, the chair. And I'm not sure what those containers are on the shelves and what their intended use is, but I can see they're covered with dust, as well.

Q. And just to complete the review of this room if we

11:26:11 can go to the next few photos maybe pausing for just a few minutes. I should say seconds. Let's not pause for minutes on each.

This is the second pill that the jury heard testimony about, and heard further testimony about powder

11:26:31 taken from that hopper being tested positive for Fentanyl.

Do you have any additional concerns -- you can hold it there -- did you have any additional concerns based on those additional photos?

A. Again, if there's Fentanyl in there because of its potency I would be concerned for the possible exposure for the people in the room either working on the drug or just even in the peripheral of the room, and the fact that it's not covered. Beyond that, the fact that it's just not in a very clean environment. It's not something that at a minimum I'm assuming these are for tablets that are being swallowed as opposed to an injectable form. Even for facilities that make pills the requirements are higher than what would be required for food.

So if an inspector were to go in and find roaches in a facility that were making pills or rodent droppings, which they do, they would be told to stop making the products at that facility until the problem was cleared up. And they may be encouraged to recall a product if it had been made and we can demonstrate anything was for risk for patients downstream or something that had already been made.

Q. Is that because a facility that produces this type of product, if it's not clean it poses a health hazard for the end user?

A. Yes.

Q. I want to ask you more generally about the new drug

application process. Does the FDA maintain records or a database for all approved new drug applications?

A. Yes. There are three databases that we have. Two of them are public, that's drugs at FDA, and what we call the orange book, and they list all of the approved products. And then there's an internal database, which is our Document Archival Reporting and Regulatory Tracking System or DARRTS. The DARRTS system, which is internal, includes a lot of proprietary information and information coming from drug companies required to an approval of their product.

Q. Speaking just to the approved applications, did you review the FDA's databases in preparation for your testimony today?

A. I did.

Q. And in reviewing the databases did you find an approved application for manufacturing or bringing to market any pharmaceuticals including Alprazolam or Fentanyl for any of the following individuals: Alex Tonge, Katie Buston, Mario Noble, Drew Crandall or Jonathan Luke Paz?

A. No. I found nothing for them.

Q. Similar question, did you find an FDA approved application for the manufacturing or bringing to market any pharmaceuticals including Alprazolam or Fentanyl for Aaron Shamo or Pharma Master?

A. I searched for both and found nothing for either.

Q. Based on your search of those drug applications, the approved ones, if it was discovered that Mr. Shamo either individually or under a pseudonym of Pharma Master was manufacturing pills scored with an A215 or M enclosed with a box with 30 on the other side, what would you conclude by the fact that he doesn't have an approved application?

A. Those are products that have been approved, and he's not listed as one of the manufacturers for them. So there's a Mallinckrodt Oxycodone product and then a Actavis Oxycodone product that meet that description that you're giving, at least what's imprinted on it.

There's another database that FDA, we like our databases. It's Electronic Drug Registration and Listing System. So that every company that's marketing a product in the United States has to list their product with us, whether it's an approved product or unapproved or illegally marketed product they still have to list it. And one of the reasons for that is so that we know it's out there in the market. And if there's ever a problem with a product we can trace it back to who made it and see what else they've made and take care of issues that might arise related to that.

So if some company was cleaning one of their machines and damaged it or left chemicals in it for the cleaning part that were ending up those chemicals ending up in the final pill form. If someone calls and says, my aunt just

died and she was taking these pills and here's the NDC code, we can look it up on the EDRLS or we can look up any other information that should be included in the prescription drug. Find out who made, where they made it. We can send our inspectors there to search. We can find out what other products are made there and might have been contaminated likewise, so it's a public health issue. And none of the names that you mentioned, either the corporate entities or the individuals are registered in EDRLS.

11:31:38

11:31:58

Q. Okay.

A. And the two products that you just described, the Mallinckrodt and the Actavis Oxycodone products EDRLS when I look to see who's responsible for labeling and manufacturing and packaging, distributing them, none of the entities you just mentioned occur there.

11:32:14

Q. FDA is essentially a regulatory agency of the federal government; correct?

A. Yes.

Q. So if none of the individuals or entities named were found in those databases do you reach a conclusion essentially as part of that regulatory agency about the individual manufacturing of those tablets?

11:32:26

A. They would be making an unapproved new drug product.

Q. Okay. Sticking to the new drug application

11:32:43

process, you yourself were I think you mentioned involved in new drug applications for at least two Fentanyl products; is that correct?

A. I was involved with all of the opioid products that were used in the operating room. But involvement can occur in a number of ways. It can be with the initial review of all the clinical studies and everything else which went along with the approval of the first new drug application which allowed the product to be marketed. And then the rest of the life of that product, life in quotes, we follow it for safety issues and make sure that there's no updates to the label, that there's no new problems that have been seen with the drug that we didn't know about before. And sometimes we have to adjust the label accordingly or sometimes we find out there are safety issues that make us take the product off the market altogether.

Q. Can you briefly explain your involvement in the product Sublimaze Preservative 3?

A. Sublimaze was one of the original Fentanyl products that was approved for injection, and that was approved before my time. So I would have been more of a caretaker for that new drug application and did not do the initial NDA reviewed.

Q. So as a caretaker what was your role relating to that product?

A. When -- if I can just take one step back. When

clinical trials are conducted to approve a drug these are big studies to show that the drugs really does what it's supposed to do with the dose that the company wants to market it for. So they get all the safety information and efficacy information. But these trials are conducted anywhere from a couple hundred to a few thousands people.

When it gets marketed it's usually used in hundreds of thousands to millions of people depending on its use. Something like Fentanyl, it's been hundreds of millions over the years. But there you're going to see very rare effects that occur with the product. Something might occur one in a million times or real rare, and some of these can be serious adverse reactions that would warrant relabeling the pill or the products, rather, or sometimes consider taking it off the market. So I was following the safety reports for that.

Sometimes the other thing that can happen is a company can come in, and it's not uncommon for them to ask to have their product approved for adults, and they do all the studies in adults. And now it's a requirement that they go back and do studies in children and submit those to us, and we decide whether or not the risks outweigh the benefits or vice versa and can approve the use for products in use for children or a different indication.

Q. Okay. So separate NDA, separate product, can you briefly explain your involvement to with Fentanyl Oralete and

what its intended purpose of use is?

A. Fentanyl Oralete is, it's like a lozenge on a stick. People used to call it a lollipop, but I don't want to use that phrase. But it's something placed between the cheek and the gums and it dissolves quickly, and the Fentanyl is absorbed through the mucous and the gums. It's used for chronic pain and acute severe pain. One of the more common uses was veterans coming back with multiple amputations or pain following exposure to explosive devices.

11:36:00 11:36:20 11:36:45 11:37:02 11:37:21

Q. Is it fair to say that that product has more of a time release aspect to it as far as the amount of Fentanyl that is transferred into the bloodstream?

A. I can't answer that question. I don't know.

Q. Okay. What other forms of Fentanyl are you aware of that FDA has approved for use?

A. So there's the injectable type which would normally be given intravenously for sometimes for patients in labor and delivery will have an epidural or other patients that are going into surgery with an epidural or spinal anesthetic, the injectable can be used there.

There's a number of sprays that are used either internasal or sublingual, under the tongue. There's lozenges. There's drug cake. Those are buccal formulations, which again are meant to be absorbed in the lining of the mouth. There's also topical products. There's the Fentanyl patch where it's

just absorbed gradually through the skin. And there's iontophoretic products where it's also basically a patch. But there's a battery supply that's there, and it uses electric current to also induce the Fentanyl to go through the skin quickly, more quickly than for a regular patch.

11:37:41

Q. And to your knowledge is there any tablet form of Fentanyl that is currently approved by the FDA?

A. There is no tablet form that's intended to be swallowed.

Q. What about crushed or snorted or smoked?

11:38:00

A. No, no and no.

Q. Okay. Of the current FDA approved forms of Fentanyl are any of those forms allowed to be used without supervision of a physician?

A. No, none of them are.

11:38:17

Q. What is your understanding of the definition of a drug under federal law, specifically Title 21 USC 351?

A. There's a special legal definition for drug, and the two most common parts are any product that's intended to prevent, treat, mitigate, cure or diagnose disease in man; and the other part would be a nonfood product that's intended to affect the structure or function of the body of man.

11:38:37

Q. Does Fentanyl meet that definition?

A. It does when it's used for its intended use for the approved products, in other words, to treat pain or prevent

11:38:57

pain. And it also meets that definition when it's used recreationally to get high.

Q. What about Oxycodone, does it fit that definition, as well?

11:39:10 A. Yes.

Q. You mentioned you're an anesthesiologist, and you've worked with previously and used Fentanyl; right?

A. Yes. On my patients.

Q. Now, I'm sorry. I missed that last part, but I'm

11:39:25 sure I need to hear it.

A. On my patients. I used Fentanyl on my patients.

Q. Oh, thank you. That is a important clarification. Let's make sure that the court reporter got that.

Just to be clear, though, in your work you haven't

11:39:41 used or dealt with Fentanyl in overdose, when someone's come into a hospital or medical setting due to Fentanyl overdose; is that correct?

A. Not to treat them. That would usually be an emergency room physician.

11:39:57 Q. How about in your experience as an anesthesiologist or otherwise, have you been called upon in the last 20 years to treat somebody with alcohol intoxication or poisoning?

A. Not to treat the intoxication itself.

Q. Okay.

11:40:20 A. Usually my interaction with those people would be

if they were in a car accident or something we're going to head to the operating room, I'd be down there to get them ready for that.

Q. So tell me and the jury what was the purpose for using Fentanyl in your practice.

A. Merely as an analgesic, a pain medicine, and that was both during the surgical procedure or some kind of invasive procedure like a colonoscopy or for labor and delivery, and also to provide pain relief for patients in intensive care or hospital setting afterwards.

Q. In your experience have you had the opportunity to observe the effects of Fentanyl on the human body on multiple occasions?

A. Yes. In the operating room setting.

Q. Are you able to quantity the number of times you've observed the effects of Fentanyl on the human body?

A. It would be several thousand.

Q. So explain what are the effects that Fentanyl has on the human body?

A. Broadly as we give it, in anesthesia we usually titrate our medications to effect. So it's not uncommon to use Fentanyl in another drug product Midazolam prior to surgery just to sedate the patient, make them comfortable. If somebody's coming in and got a broken arm and it's going to be set in the operating room, the Fentanyl would provide the

analgesia for something like that.

As you start to induce anesthesia, actually put the patient to sleep for the surgical procedure, if you're using Fentanyl to provide some pain relief during the procedure you'll see that they start to breath more slowly, they're breathing more shallow, their pupils will constrict. And eventually they'll stop breathing if you give enough Fentanyl. Usually by that point, though, we've given them another medication like Propofol and make them go off to sleep and unconscious altogether, and we've taken over the airway.

Q. What do you mean by taking over the airway?

A. So if a patient receives enough opioid as I said they'll start to breath more shallowing and less frequently, and what happens is the carbon dioxide in the blood will build up and the amount of oxygen decreases, and if you don't do something, you don't intervene they'll die. So we manage the airway. We assist with their breathing. Sometimes initially we'll put a mask with oxygen coming through it. It's hooked up to an anesthesia machine which has a ventilator on it. It also has a bag hanging from it so we can gradually squeeze the bag and help move air in and out of the lungs. Once general anesthesia has been induced and the patient is, well, they're unconscious and they're paralyzed, we put a breathing tube into the windpipe, the trachea, and we hook them up to the anesthesia machine later, and we breath for them.

Q. Is the slowing of the breathing, kind of what you describe, is it correct to use the term respiratory depression?

A. Yes. That would be the technical term for it.

11:43:35 Q. In your experience, when you're administering Fentanyl to a patient do you request or monitor the blood Fentanyl levels to determine the amounts of amounts of Fentanyl in the blood?

A. No.

11:43:44 Q. Why not?

A. We -- I guess two reasons. One, we treat the patient, not a number, from a blood level. So whatever the patient needs they get. If I give a little bit and that's adequate, I don't care what the blood level number is. The

11:44:01 patient has enough analgesic, you leave them well enough alone. Some people who has a lot more painful condition, car crash, multiple broken bones or cancer patient, then they require a lot more Fentanyl for what a typical level might show for an analgesic effect. So you give them what they

11:44:18 need. So you treat the patient, not a number.

And the other part to that is that if you are giving a lot and the patient should be more sensitive to the Fentanyl than you would expect you've got everything there to deal with that situation. I can support the airway primarily.

11:44:35 Q. So as a physician, as an anesthesiologist, would

you leave somebody alone that you've begun to give Fentanyl to?

A. No.

Q. Do you know the blood Fentanyl -- this may be inherent in your prior answer. But do you know the blood Fentanyl levels that are effective versus potentially toxic?

A. No, I don't.

Q. Does that go beyond the scope of your practice over the years?

A. It goes beyond the scope of the practice. But even in a new drug application it goes beyond the scope of what would be required for that.

Q. You mentioned that essentially you don't observe or request the blood Fentanyl levels. Do you -- in providing Fentanyl to a patient do you monitor the dosage?

A. We record the dose. So normally what you would do, first of all, the patient has monitors on them. They've got a blood pressure cuff, a pulse oximeter which measures the oxygen levels in the blood. That's what we worry about in terms of what levels. We measure their hear rate. We have a electrocardiograph monitor so we watch the rhythm of the heart. And there's some other monitors following general induction of general anesthesia. So that helps guide us in terms of patient safety. And then just watching the patient's response.

If I give Propofol to put someone to sleep, I start out with a low dose. Same thing with Fentanyl, just to see how the patient responds. If I'm not getting an adequate response, I give more. And I keep giving more gradually until I have the right amount. If for some reason I've overshot, then I'm prepared to treat that. When I say I, I mean we as anesthesiologists and nurse anesthetists.

Q. What's a typical range of an appropriate dosage that you're using in that setting?

A. That varies based on a lot of issues. So it depends on the amount of pain you anticipate for a procedure. Someone coming in for cataract surgery, which is an operation on eye, they may need a very low dose of Fentanyl. Typically they're older people, as well, so they might be a bit more sensitive to Fentanyl. So you might give them 50 micrograms. For most healthy young people a does of 100 micrograms. They'll feel a bit wheezy and willing to go to sleep without much effort. For someone that's coming in for open heart surgery, at least back in the day when we used Fentanyl for that, they could get several milligrams of Fentanyl. The does varies widely depending on the intended use.

THE COURT: I want to shift gears on you. What types of substances are usually found in pills that are manufactured and approved by the FDA? Just the general categories of substances.

A. I would say there's three things that you'll find in pretty much every drug over the counter and prescription. So you have the active ingredient, and that's the ingredient that does the work of the drugs. It lowers the blood pressure, kills bacteria, open airways and asthmatic. And then you have the inactive ingredient, and those are the things that make the active in a usable form. So if it's a powder you're going to inject you may dissolve it in something. You may want to add a preservative to prevent bacteria from growing in it. If it's a pill you've got this powder, you need to make it something that you can compress into the size and shape that someone can actually take.

The other thing that occurs in all of these is nothing is 100-percent pure. And the impurities are something that poses substantial concern to us at FDA. It can propose a significant risk to the patient.

Q. How does the FDA regulate the contents of prescription pills?

A. So this goes back to what we were talking before about the manufacturing chemistry and MC controls part of the new drug application. So the ingredients that someone buys to make a drug product, they buy it from some firm in China. It comes in. And it's supposed to be salt, it supposed to be 99 percent pure. So every ingredient that goes in a drug product, whether it's over the counter or prescriptions drug

product, the company is required to test that ingredient when they get it to make sure it really is what it says it's supposed to be and it's as pure as it's supposed to be.

When the product is finally made, the finished drug product, the company again has to again retest it and look to make sure that it's within specification. So not only do you have these ingredients, a lot of times the medicines are made by a series of chemical reaction. They just mix the stuff in batches. And oftentimes those reactions don't go all the way. So you still have a little bit of some of the initial ingredients in there. They're not going to help with the drug product be effective. They're not one of the inactive ingredients, so those would be considered impurities, and some of those can be very toxic.

Q. If a manufacture, a pill tablet manufacturer, wants to change one of the ingredients, can they just do that on their own and without any grief from the FDA?

A. They need to notify us in advance. And sometimes they need to do special testing. So these impurities, things like benzene, which is carcinogenic, stuff like that that you find in a lot of compounds, they have to be within a certain level. If it's a small enough range you have to think it's like 99.8 percent pure, it comes down to dose amounts, they may not have to do anything about it. And when they've tested their product in humans initially, it's that finished product.

So you have a sense of the safety with that. It's also tested in animals before it goes to humans.

If they tweak the product putting in a new inactive ingredient, they have to reconsider all of these things. Again, does that new active ingredient interact any way with the other ingredients that are there? Does it make the pill less effective? Less safe? Does it introduce some new risk?

And just so you know, usually we worry about interactions with active and inactive ingredients. We also worry about reactions of the finished products with the container it's in. Sometimes we found that when pills are put in plastic containers some of the components in that plastic leach into the pills. We even found that pills that are kept in glass containers, which was a surprise to us, some of the components, boron in particular, in glass leaches into the pills. So this almost interaction that goes on over the course of the lifespan of the drug before it expires, and we keep track of all of that. So the small changes or what appear to be small changes have to be vetted by the FDA.

Q. Previously you mentioned two manufacturers that create Oxycodone pills, Mallinckrodt and Actavis. Do you know what the active ingredients are in each of their products?

A. Oxycodone is the active ingredient.

Q. Do you know what quantity of Oxycodone is in each of those pills? Maybe I better specify. The A215 from

Actavis and the M30 from Mallinckrodt, do you know what the --

A. Those are 30 milligram formulations.

Q. In either one of those products should there be any Fentanyl found?

11:52:23 A. No.

Q. I want to show you -- you mentioned packaging, and I want to show you one of our exhibits. If we can look at Government's Exhibit 7.83.

THE COURT: What is it?

11:52:38 MR. BURGGRAAF: It's 7.83. Photo 1 and 2. We can stop on Photo 1 for a moment.

Q. BY MR. BURGGRAAF: The jury's heard testimony that what's being depicted here is a package that was seized from the Tonge/Bustin porch on November 18, 2016.

11:53:06 And, Yvette, would you mind zooming in on the invoice there?

This is the invoice that the jury heard testimony about that was included within the package.

And, Yvette, if you'll zoom out now.

11:53:25 Dr. Simone, based on your experience of the FDA what are the issues that we're looking at here with packaging or other regulatory issues that the FDA deals with?

A. I couldn't read all the information on that invoice, just the name of the coffee company. But if this is

11:53:48 something that was actually delivered to the end user those

plastic bags that's included, those would be considered the immediate container. Per FDA regulations they would have to be determined whether or not there's any interaction with the pills contained in those bags and the bags themselves. There's no labeling on the bags to say what it is, who made it, how to contact someone if there is a problem with it. There's no listing of active and inactive ingredients in it. In short, these would be misbranded drug products.

11:54:09

Q. And if we could go to Photo 2. Similarly the jury has heard testimony -- they heard testimony that the pills from that first photo contained Fentanyl. The jury heard testimony this was another package that was picked up from that same night from the same location. Similar issues that -- similar issues is what you described previously?

11:54:30

A. Again, this is intended for the end user. There's no labeling on the bags. And again, the concern about interactions between the bags and the product itself.

11:54:49

Q. To clarify, so Oxycodone doses, are they most routinely measured in milligrams?

A. For the approval oral products, yes, they're milligrams.

11:55:17

Q. And how are Fentanyl doses measured?

A. They're measured in micrograms.

Q. So the metrically challenged, what is the equivalent of micrograms to 1 milligram?

11:55:30

A. There are 1,000 micrograms in 1 milligram.

Q. And your testimony previously was that 100 micrograms, so a 10th of a milligram would be an appropriate Fentanyl dosage to start out with for an adult in your practice?

11:55:49

A. Correct. It would can a common dose that would be administered.

Q. How does the potency of Fentanyl and Oxycodone compare?

11:55:59

A. Fentanyl is multiple times more potent than Oxycodone on a weight-by-weight basis. If you wanted to get a similar analgesic effect for the two products, you would have to give anywhere from 10 to 100 times or maybe even 1,000 times more Oxycodone than Fentanyl.

11:56:23

MR. BURGGRAAF: If I can have a moment, Your Honor?

THE COURT: You may.

(Time lapse.)

Q. BY MR. BURGGRAAF: Sticking with what you just mentioned as far as the potency, I want to give you some

11:56:51

hypotheticals dealing with potency that compare Oxycodone to Fentanyl.

If you have an individual who takes 30 milligrams of Oxycodone either orally or by crushing and snorting or smoking it, how likely is it that they will suffer serious

11:57:10

adverse health consequences or death as a result?

30 milligrams of Oxycodone to clarify.

A. That's going to depend on a number of factors. If you're giving it to an infant, if you're giving it to a 98-year-old that has a lot of medical problems you're going to have a lot more risk associated with that than a healthy young adult. But for most healthy adults, they would probably tolerate the 30 milligram dose with minimal side effects.

Q. And yet to be clear, the FDA has approved an Oxycodone pill in a 30 milligram quantity?

A. They have, to treat pain.

Q. If an individual takes by comparison 30 milligrams of Fentanyl either orally or by crushing and snorting or smoking it, how likely is it that they will suffer serious adverse health consequences or death as a result?
30 milligrams of Fentanyl to qualify.

A. It's extremely likely they'll die unless there is some type of intervention beforehand.

Q. So those two examples, do those help, then, to accurately depict the difference in potency between 30 milligrams of Oxycodone versus 30 milligrams of Fentanyl?

A. One way to show it.

Q. How about a dosage of only 1 to 4 milligrams of Fentanyl, how likely is it that an individual, an average adult would suffer from adverse health consequences or death?

A. Again, in all likelihood if there's no intervention

they would die. And if I can just explain my thinking on that a little bit?

Q. Yes.

A. Back many years ago when I was in practice patients coming in for heart surgery, bypass grafting, valve repairs, they had very fragile hearts. They couldn't tolerate much stress one way or the other. And that includes the stress of inducing anesthesia. But Fentanyl is what we call a very hemometrically dynamic stable drug. It doesn't affect blood pressure, heart rate much. And often time we would give these patients masses doses of Fentanyl. And that would be sufficient for them to undergo the heart procedure up to the point where they were put on heart bypass. And by that I mean the surgeon was able to make an incision down the sternum below the chest, and take a bone saw, cut that bone in half and split the chest open and all without an increase in heart rate or blood pressure. And that would typically take 50 micrograms per kilogram in an adult.

So a 70 kilogram adult, which was 154 pounds, they would get 3 1/2 milligrams of Fentanyl. An 80 kilogram adult, someone that's 176 pounds, they would get 4 milligrams of Fentanyl. And while we're pushing that drug, it's a massive volume of Fentanyl. They start -- you start to see all the side effects. In particularly, the respiratory depression, they stop breathing. And that's normal before we get to the

end of the dose. You'll see that after a couple hundred milligrams. But we're ready to intervene that.

Q. To qualify, you start seeing those symptoms after a couple hundred milligrams --

12:00:41 A. Yes.

Q. -- or micrograms?

A. I'm sorry. Micrograms.

Q. And in that scenario they would die unless there was intervention as far as the breathing aspect of it.

12:00:53 A. Correct.

Q. So jumping back to that example of maybe 1 to 4 milligrams of Fentanyl you stated that there was a likelihood of suffering serious adverse health consequences or death if there wasn't intervention. If that individual was drinking a

12:01:12 fifth of vodka or alcohol would that generally change the risk of death or adverse health consequences?

A. No. The alcohol is also a respiratory depressant, so it might hasten death. But it would be more the icing on the cake than the cake. The Fentanyl would be the chief part

12:01:34 for that.

MR. BURGGRAAF: No further questions.

THE COURT: Cross-examine?

MR. SAM: I have no questions, Your Honor.

THE COURT: Thank you. You may step down. And you

12:01:46 can be excused.

And we'll take a lunch break about 30 minutes.

(Whereupon, the jury left the court proceedings.)

THE COURT: We'll be in recess for about 30 minutes.

12:02:26 (Whereupon, requested testimony concluded.)

* * * * *

STATE OF UTAH)
) ss.
COUNTY OF SALT LAKE)

I, KELLY BROWN HICKEN, do hereby certify that I am a certified court reporter for the State of Utah;

That as such reporter, I attended the hearing of the foregoing matter on August 22, 2019, and thereat reported in Stenotype all of the testimony and proceedings had, and caused said notes to be transcribed into typewriting; and the foregoing pages number from 4 through 119 constitute a full, true and correct report of the same.

That I am not of kin to any of the parties and have no interest in the outcome of the matter;

And hereby set my hand and seal, this ____ day of _____ 2019.

_____
KELLY BROWN HICKEN, CSR, RPR, RMR